

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/24/2020 4:46:06 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] (b) (6); Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [(b) (6) Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Johnson, Robert (OS/ASPR/BARDA) [(b) (6) Kramer, Lynn [(b) (6)]; Lane, Cliff (NIH/NIAID) [E] [(b) (6) Marks, Peter (FDA/CBER) [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6) Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plump, Andy [(b) (6) Rasi, Guido [(b) (6) Reed, John [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [(b) (6)]; Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Woodcock, Janet (FDA/CDER) [(b) (6) Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Freire, Maria (FNIH) [T] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Gonzalez, Nina [(b) (6) Kim, Elizabeth [(b) (6) Stratton, Ben [(b) (6) Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6) Rachel Ramoni [(b) (6) Plenge, Robert [(b) (6) Talley, Michael [(b) (6) Cavaleri, Marco [(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6)]; Culp, Michelle (NIH/OD) [E] [(b) (6)]; Tsai, John [(b) (6) [(b) (6)]
CC: Barasch, Kimberly (NIH/NIAID) [C] [(b) (6)]; Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6)]; Carver, Trea (NIH) [C] [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [(b) (6) Hoffstetter, Renata (FNIH) [T] [(b) (6) Iberdemaj, Vaide [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6)]; McManus, Ayanna (NIH/OD) [E] [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Protasiewicz, Ann [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Thomas, Ashley (FDA/CDER) [(b) (6) Wood, Gretchen (NIH/OD) [E] [(b) (6) Sepulveda, Dorina (FNIH) [T] [(b) (6) FNIH Central Account [(b) (6) Li, Rose [(b) (6) Zottoli, Jessica [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Gladman, Jordan (NIH/OD) [E] [(b) (6) Elsaid, Olivia [(b) (6) Castillejos zenteno, Carlos [JRDUS] [(b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6) Burklow, John (NIH/OD) [E] [(b) (6) Wolinetz, Carrie (NIH/OD) [E] [(b) (6) Myles, Renate (NIH/OD) [E] [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6) Chen, Helen [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) Meltzer, Abbey (FNIH) [T] [(b) (6) Gorman, Greta (FNIH) [T] [(b) (6) Dana Carluccio [(b) (6)]

Subject: ACTIV Response Partnership Leadership Team Meeting #4
Location: <https://fnih.zoom.us>, (b) (6)
Start: 6/3/2020 4:00:00 PM
End: 6/3/2020 5:30:00 PM
Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramoni; Plenge, Robert; Talley, Michael; (b) (6); Cavaleri, Marco; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Gibbons, Gary (NIH/NHLBI) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Treia (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; FNIH Central Account; Li, Rose; Zottoli, Jessica; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Castillejos zenteno, Carlos (JRDUS); Dimishkov, Roxanne (NIH/NHLBI) [C]; Burklow, John (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Chen, Helen; Lowy, Douglas (NIH/NCI) [E]; Meltzer, Abbey (FNIH) [T]; Gorman, Greta (FNIH) [T]; Dana Carluccio

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From: Tountas, Karen (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 4/27/2020 6:54:39 PM
To: Bascles, Lionel [(b) (6)]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6)]; Wachtel, Jonathan [(b) (6)]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)]; Jansen, Kathrin [(b) (6)]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaefe06ebd70-parkeras]; Carluccio, Dana [(b) (6)]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6)]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6)]; Hamilton, Nancy [(b) (6)]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [(b) (6)]; Mueller-Reichenstein, Petra [petra. (b) (6)]; Quadros, Nora [(b) (6)]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Hill, Zoe (NIH/NHLBI)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]

Subject: Clinical Trial Capacity Working Group Meeting #4 Summary

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting #4_Summary_Draft-FINAL.pdf

Dear Clinical Trial Capacity WG Members,

Attached is the summary for the full working group meeting that took place last week (Friday, April 24). The next WG meeting is scheduled for tomorrow, Tuesday, April 28 at 9am EST.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

(b) (6) | fniih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 11:37:18 PM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [(b) (6)]
Subject: Initial Follow-up to ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12
Attachments: ACTIV_Therapeutics-Clinical_Agent Prioritization Subgroup_21May2020_Key Takeaways.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the initial follow-up to today's meeting. High level summary and action items are included, as well as a list of the members of the sub-teams for review. Please take a look and let me know if you would like to move sub-teams or be assigned to one.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; (b) (6)

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(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];

(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Hewitt, Judith (NIH/NIAID) [E] [(b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];

(b) (6) (b) (6) (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];

(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Ottinger, Elizabeth (NIH/NCATS) [E] [(b) (6) (b) (6) (b) (6) Rao, Srinivas /US [(b) (6)

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 Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li
 [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
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 [(b) (6) Dave Frankowski [(b) (6) Diamond, Michael
 [(b) (6)

Location: https://fnih.zoom. (b) (6)

Start: 4/24/2020 3:00:00 PM

End: 4/24/2020 4:00:00 PM

Recurrence: (none)

Required Attendees: (b) (6) (b) (6) (b) (6) (b) (6)
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 Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter
 (OS/ASPR/BARDA); Rao, Srinivas /US

Optional Attendees: Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];
 Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E];
 Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam,
 Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel,
 Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha
 (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D;
 Dave Frankowski

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 2/27/2021 4:58:10 PM
To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowy]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell (b) (6) [(b) (6) (b) (6) Cavalieri Marco (b) (6) mmdavis [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user87932049]; (b) (6) Greg Glenn (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56f8be4598a57b423d484dcf9f-offit.email]; (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) Tal Zaks [(b) (6)
CC: Tolman, Brett [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; (b) (6) Hopps, Markay [(b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) Jeneffer Haynes (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; (b) (6) Isabel Ramsey [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Dieffenbach, Carl (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94acc37973d346fa98dfe16cd1bf7013-cdieffenba]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T]

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 (b) (6) Paul Gillard [(b) (6) François P Roman [(b) (6)
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 rose.li@rosellassociates.com; dana.carl (b) (6) Bethany Stokes
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 [(b) (6) Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: Notes from the ACTIV Vaccines Working Group meeting

Attachments: ACTIV.SARS.Variants.2.21.pptx; 2021-02-22 Vaccines Working Group meeting Summary Notes.docx

Dear Vaccines Working Group members,

Thank you for your participation in our meeting this past week. The slides that Doug presented to frame the discussion are attached along with the meeting notes. The updated FDA guidance that Peter Marks referenced in the meeting is [here](#).

At the end of the meeting, Larry challenged the group to consider the criteria for introducing new vaccines in response to variants with greater granularity. Some potential questions are included on page 7, and everyone is invited to share their perspectives or interest in further discussion.

We are currently working on scheduling our next meeting, which is planned to focus on the potential epidemiological impact of variants.

Please do not hesitate to share any questions or comments.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Sunday, February 21, 2021 5:26 PM
Subject: Agenda and notes for ACTIV Vaccines Working Group meetings

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Monday) at 12pm ET / 9am PT / 6pm CET.

The topic for this meeting is a discussion of what information we need to acquire before adding vaccination against a variant strain to a country/region's vaccination strategy. Doug will initiate the conversation then invite perspectives from the participants.

Notes from Thursday's meeting are attached. We sincerely thank Penny and Alex for their presentations on the implications of the 501Y.V2 variant for natural and vaccine-derived immunity and the cross-neutralization of responses to 501Y.V2 infections against ancestral virus. In addition, Joe Menetski's slides on the new ACTIV Tracking Resistance and Coronavirus Evolution (TRACE) Working Group are attached, and anyone interested in more information or participating should feel free to reach out to Joe (b) (6)

We welcome additional comments and questions any time.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, February 17, 2021 6:25 PM
Subject: Agendas and notes for ACTIV Vaccines Working Group meetings

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Thursday) at 2pm ET / 11am PT / 8pm CET.

The topic for this meeting will be antibody immunity to 501Y.V2 through vaccination and infection, with presentations from Penny Moore (South Africa's National Institute of Communicable Diseases) and Alex Sigal (Africa Health Research Institute).

Our third meeting on the topic of viral variants will be Monday, 22 Feb. The agenda for that meeting is a discussion of what information we need to acquire before adding vaccination against a variant strain to a country/region's vaccination strategy. Doug will initiate the conversation then invite perspectives from the participants.

Notes from our first meeting on this topic are attached, with appreciation again to Trevor Bedford and Jesse Bloom and for the many contributions of meeting participants.

Finally, we wanted to provide an update on the concept of a trial to assess the impact of vaccination on infection transmission and viral load, which we discussed in meetings in late 2020. A modified version of the protocol that we discussed has been supported to move forward. The trial plans to enroll 12,000 students including at HBCUs, split between immediate-vaccination and delayed-vaccination arms (substituting delayed vaccination for placebo eased regulatory requirements), with daily viral sampling and contact tracing of infections as possible.

As always, please reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Thursday, February 11, 2021 2:59 PM
Subject: Slides from today's ACTIV Vaccines Working Group meeting

Hi all,

Thanks again to Trevor and Jesse for their insightful presentations and to everyone who participated in the meeting. Trevor and Jesse have kindly made their slides available at:

- <https://bedford.io/talks/sars-cov-2-molecular-evolution-activ/#/> (advance with space-bar or arrows)
- <https://slides.com/jbloom/sars-cov-2-activ>

We will be following up with meeting notes, and will send an invite for our next meeting as soon as we can.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, February 9, 2021 5:54 PM
Subject: Agenda for the next ACTIV Vaccines Working Group meeting (Thurs, 11 Feb)

Dear Vaccines Working Group members,

We're looking forward to our next meeting, Thursday at 11:30am ET / 8:30am PT / 5:30pm CET. Please note that this meeting is scheduled for 75 min to allow for more discussion.

The topic for this meeting (and planned subsequent meetings) is the evolution of viral variants and the implications for vaccines. For our meeting Thursday, Jesse Bloom and Trevor Bedford of Fred Hutch will join us to present on the genetics of the epidemic and predictive analytics, followed by discussion during which we welcome participants to share the activities that their organizations are undertaking in response.

As always, please reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Sunday, December 13, 2020 7:11 PM
Subject: Agenda for the next ACTIV Vaccines Working Group meeting (Monday, 14 Dec)

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Monday) at 12pm ET / 9am PT / 6pm CET.

The main agenda item for tomorrow is discussion of potential approaches to evaluate the impact of vaccines on transmission. This topic was presented and discussed at the 18 Nov meeting of the Vaccines Clinical Trials Sub-Group. If you were unable to join that meeting (or to refresh your memory), the notes with presentation materials embedded are attached.

If we have additional time after that discussion, we may discuss Working Group member perspectives on the other topics that have been discussed recently in the Clinical Trials Sub-Group: the potential for blinded cross-over within studies (30 Nov, notes attached) and evaluating vaccines in immunocompromised populations (10 Dec, notes still to come).

If you cannot join the meeting but would like to provide input on any of the topics above, please send it to us prior to Wednesday, when Doug will be reporting on behalf of the group to the ACTIV Leadership Team.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, November 18, 2020 7:13 PM
Subject: Notes from the ACTIV Vaccines Working Group meeting

Dear Vaccines Working Group members,

With apologies for the delay, attached are notes and the single slide from last week's Vaccines Working Group meeting.

After the meeting, the Working Group and Sub-Group leadership aligned on the immediate priorities for discussion. Those begin today with the Vaccine Clinical Trial Sub-Group's meeting on evaluating the impact of vaccines on transmission. Topics prioritized for subsequent discussions include potential blinded cross-over for ongoing phase 3 trials, preparing for the possibility of vaccine efficacy varying by platform/product, and evaluating vaccines in immunocompromised populations. Invitations for meetings on those topics will be sent soon.

As always, we welcome additional comments and questions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, November 10, 2020 1:33 PM
Subject: Agenda for tomorrow's ACTIV Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Wednesday) at 1pm ET / 10am PT / 7pm CET. We scheduled this meeting last week without knowledge of yesterday's exciting announcement, and are delighted to be re-convening this group at such an auspicious time.

As we described below, the agenda for tomorrow is an open discussion of the priorities for vaccines in addition to the licensure studies that the Vaccines Working Group or the Clinical Trials Sub-Group should consider. Some members of the group have already proposed a few ideas, and all members of the group are invited to make additional suggestions and weigh in on the potential opportunities. After the meeting we will prioritize next steps.

If you cannot attend tomorrow's meeting, as always please feel free to submit ideas in advance that we can share on your behalf or send feedback on the notes afterwards.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Friday, November 6, 2020 1:01 PM
Subject: Next ACTIV Vaccines Working Group meeting: Weds, 11 Nov

Dear Vaccines Working Group members,

As you may recall from the summer, we agreed to stop regular meetings of the Vaccines Working Group and reconvene as needed. Our next meeting will be Wednesday, 11 Nov, at 1pm ET (10am PT / 7pm CET).

We've been requested by ACTIV leadership to have a discussion about the priorities for vaccines in addition to the licensure studies. The Vaccines Clinical Trials Sub-Group has had previous meetings on the topics of evaluation in

pregnant and pediatric populations, and is planning upcoming conversations about studying impact on transmission and evaluation in immunocompromised populations, as well as a discussion of the potential application of expanded access protocols.

At our next Working Group meeting, we would appreciate input on those and other potential priorities for discussion within the group. We are looking forward to your thoughts, and as always appreciate any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
(b) fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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Subject: Follow-up to ACTIV TX-Clinical Master Protocol Subgroup Meeting #11

Attachments: ACTIV Therapeutics-Clinical MP Sub-Group Meeting 11 Key Takeaways 05012020.pdf; REMAP-COVID Simulation Document - 28 April 2020 DRAFT[1].pdf; REMAP-CAP design and rationale (in press) (1).pdf; REMAP-COVID core protocol V.2.0.pdf; ms_4-30.pdf

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the follow-up materials from yesterday's meeting.

1. The summary of key takeaways and action items from the discussion. Please let us know if we have missed anything critical.
2. The documents for REMAP-COVID for review for our conversation with that team next Friday.
 - a. REMAP-COVID core protocol
 - b. REMAP-CAP rationale
 - c. REMAP-COVID simulations

3. Meta-analysis manuscript for the combination of data from remdesivir trials that Lisa discussed from the PI at UNC. This was discussed in the context of potentially considering a partially synthetic control arm for our trial if we are having challenges with getting remdesivir for SoC.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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CC: Tountas Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Materials for ACTIV TX-Clinical Master Protocol Subgroup Meeting #16
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_13May2020 Meeting Guide.pdf

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the slides for our portion of the meeting tomorrow. The presentation slides from I SPY will be shared on the call from their group.

We are going to try to keep the I-SPY presentation to no more than 40 minutes, including questions so we can discuss a few necessary matters for next steps on our trials.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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Sent: 5/23/2020 4:59:02 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Carrier (b) (6); Eric Hughes (b) (6); LaVange, Lisa M (b) (6); Sandeep Menon (b) (6); Proschan, Michael (NIH/NIAID) [E] (b) (6); Read, Sarah (NIH/NIAID) [E] (b) (6); Price, Dionne (FDA/CDER) (b) (6); Rubin, Daniel B. (FDA/CDER) (b) (6); Farley, John (FDA/CDER) (b) (6); Karen Lynn Price (b) (6); Eron, Joe (b) (6); Javan, Arzhang (NIH/NIAID) [E] (b) (6); Roa, Jhoanna (b) (6); Kim, Peter (NIH/NIAID) [E] (b) (6); Kozak, Marina (OS/ASPR/BARDA) (b) (6); [Marina. (b) (6)]
CC: Demarcus (b) (6); Tountas, Karen (FNIH) [T] (b) (6); Wachtel, Jonathan (b) (6); Elizabeth Kim (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6); [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa (b) (6); Eron, Joseph J Jr (b) (6); Smith, David (b) (6); Paul Klekotka (b) (6); Ajay Nirula (b) (6); . Chen, Helen Q. (b) (6)
Subject: ACTIV-2 Writing Team Meeting
Location: <https://fnih.zoom.us> (b) (6)
Start: 5/26/2020 6:00:00 PM
End: 5/26/2020 7:00:00 PM
Show Time As: Busy

Required Attendees: Judy Carrier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6); (b) (6); (b) (6); (b) (6); Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6); Kim, Peter (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

Stacey Adam is inviting you to a scheduled Zoom meeting.

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Sent: 4/15/2020 3:10:08 PM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fdi]; Draghia-Akli, Ruxandra [E] (b) (6) Eisner, Mark [E] (b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [E] (b) (6) Judy Currier [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [E] (b) (6) LaVange, Lisa [E] (b) (6) Levy, Elliot [E] (b) (6) Mellors, John W [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [E] (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [naimish.patel@sanofi.com]; Peppercorn, Amanda [E] (b) (6) Poole, Mike [E] (b) (6) Proschan, Michael (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Price, Dionne (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [E] (b) (6) Jansen, Kathrin [E] (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [E] (b) (6) Biggs, Mary [E] (b) (6) Butcher, Tina [E] (b) (6) Demarcus [E] (b) (6) Macone, Erin [E] (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [E] (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [E] (b) (6) Tolman, Brett [E] (b) (6) Alvarez, Rosa [E] (b) (6) Gonzalez, Nina [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Anderson, Margaret [E] (b) (6) m]; Lucas

Smalldon [(b) (6) GMM [(b) (6) JKR [(b) (6) Peppercorn,
Amanda [(b) (6)
Subject: Time Sensitive Response Needed: Poll to Help Schedule Future TX-Clinical WG and Subgroup Meetings

Dear ACTIV Therapeutics-Clinical Working Group Members,

To help streamline scheduling, please view the following link to indicate your availability for upcoming larger WG and sub-group meetings: <https://doodle.com/poll/nhd5zgimn537qgk5>. Moving forward, we plan to have one large WG meeting per week for 90 minutes on Mondays, and two 1 hr sub-group meetings per week, per sub group, on Tuesdays, Wednesdays, or Thursdays. **Please submit your responses no later than 10PM EST, Thursday, 4/16.**

Agent Prioritization Sub-Group members: Kindly indicate all times during which you can be available for the full WG meeting next Mon and sub-group meetings next Tuesday, Wednesday, and Thursday. We will select times that work best for group members. **Please also indicate your availability for this Friday, 4/17,** as there may be a need for an additional meeting this week

Master Protocol Sub-Group members: Kindly indicate all times during which you can be available for the full WG meeting next Mon and sub-group meetings next Tuesday, Wednesday, and Thursday. We will select times that work best for group members.

Once you click the link, you can add your name to the empty "Name" field, and check the boxes for all times you can be available. Please note that times are in Eastern Standard Time (EST). If you have any questions or need further assistance, please contact Elizabeth Kim (b) (6) (b) (6) directly.

Thank you,
Stacey Adam

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) , Mobile: (b) (6)
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 5/21/2020 9:55:18 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: Slides for ACTIV TX-Clinical Working Group Meeting #7

Can we chat around 8:30 tomorrow a.m.? And I think we should send LT some kind of short alert tomorrow afternoon about some directives that may not be met cause ICs are doing their own thing anyway, unless they want to intervene with a strong directive. Personally I think this partnership should readjust to go wherever it looks like it can be most helpful and try not to bring sailed ships back, but I tend to be pessimistic about success of central control.

From: Culp, Michelle (NIH/OD) [E] <(b) (6)>
Sent: Thursday, May 21, 2020 4:24 PM
To: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Subject: RE: Slides for ACTIV TX-Clinical Working Group Meeting #7

No, so thanks for sending. I will request Stacey and Mike to add me to the Therapeutics Clinical and Vaccine WG calls. Do you want to chat this evening or tomorrow morning?

From: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Sent: Thursday, May 21, 2020 4:01 PM
To: Culp, Michelle (NIH/OD) [E] <(b) (6)>
Subject: FW: Slides for ACTIV TX-Clinical Working Group Meeting #7

Did you get this in time to join today? I did. You should try to follow this group. They mostly talked about their plans for a master protocol for the mAbs and I'm sure you would get more out of the details. But I have some observations (not urgent to discuss).

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Thursday, May 21, 2020 12:44 PM
To: Bozzette, Sam (NIH/NCATS) [E] <(b) (6)> Butterson, Joan <joan (b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)> Draghia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith <(b) (6)> Hughes, Eric <(b) (6)> Judy Currier <(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)> Levy, Elliot <(b) (6)> Mellors, John W <(b) (6)> Menon, Sandeep <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Patel, Naimish <(b) (6)> Peppercorn, Amanda <(b) (6)> Poole, Mike <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)> Collins, Sylvia (FDA/CDER) <(b) (6)> Amanda Peppercorn <(b) (6)> Garner, Carl <(b) (6)> <garner_carlos (b) (6)> Higgs, Elizabeth (NIH/NIAID) [E] <(b) (6)> Koroshetz, Walter (NIH/NINDS) [E] <(b) (6)> Burgess, Timothy <(b) (6)> Reineck, Lora (NIH/NHLBI) [E] <(b) (6)> Aggarwal, Neil (NIH/NHLBI) [E] <(b) (6)> Rosenberg, Yves (NIH/NHLBI) [E] <(b) (6)> Brown, Jeremy (NIH/NINDS) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Cc: Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Young, John <(b) (6)> Biggs, Mary <(b) (6)>

Butcher, Tina (b) (6) Demarcus < (b) (6) Macone, Erin
 < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Salathin, Carla
 < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Menetski, Joseph (FNIH) [T]
 < (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Wachtel, Jonathan < (b) (6)
 Tolman, Brett < (b) (6) Alvarez, Rosa < (b) (6) Gonzalez, Nina
 < (b) (6) Dana Carluccio < (b) (6) Rose Li Central Account
 < (b) (6) Anderson, Margaret < (b) (6) Lucas Sma Idon
 < (b) (6) Stratton, Benjamin < (b) (6)
 (b) (6) Mollica, Linda /US < (b) (6) Qashu, Felicia (NIH/OD) [E]
 < (b) (6) Patterson, Amy (NIH/NHLBI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E]
 < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6)

Subject: Slides for ACTIV TX-Clinical Working Group Meeting #7

Dear ACTIV TX-Clinical WG,

Looking forward to seeing you all soon at the meeting. Please find attached the slides for the meeting.

Thanks,
 Stacey

Stacey J. Adam, PhD
 Director, Cancer
 Research Partnerships
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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 12/9/2020 7:38:38 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];
(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6)]; (b) (6)
Arvin, Ann [(b) (6) (b) (6) Cavaleri Marco [(b) (6) (b) (6)
(b) (6) mmdavis [(b) (6) (b) (6) Greg Glenn
[(b) (6) (b) (6) Haynes, Barton [(b) (6) (b) (6)
(b) (6) Marks, Peter (FDA/CBER) [(b) (6) Mascola, John (NIH/VRC) [E]
(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Nelson Michael
[(b) (6) Offit, Paul [(b) (6) (b) (6) Seals, Jonathan
(OS/ASPR/BARDA) [(b) (6) (b) (6) (b) (6) Tal Zaks
[(b) (6) Beth Bell [(b) (6) [(b) (6)
CC: btolman [(b) (6) (b) (6) Hopps, Markay [(b) (6)
Kozlowski, Mary (NIH/NCI) [C] [(b) (6) Johnson, Maureen (NIH/NCI) [E]
(b) (6) (b) (6) Jeneffer Haynes [(b) (6)
(b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]
[(b) (6) .gov]; (b) (6) Isabel Ramsey [(b) (6) Parker,
Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary
(NIH/NIAID) [E] [(b) (6) Erbeling, Emily (NIH/NIAID) [E] (b) (6) ; Deffenbach,
Carl (NIH/NIAID) [E] [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6) Culp, Michelle
(NIH/OD) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Wholley, David (FNIH) [T]
[(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Menetski, Joseph (FNIH) [T]
(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6)
James, Stephanie (FNIH) [T] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6)
Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6) Kurilla, Michael
(NIH/NCATS) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Paul Gillard
[(b) (6) François P Roman [(b) (6) Hamilton, Holli (OS/ASPR/BARDA)
[Holli. (b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)
[(b) (6) Kathleen Neuzil [(b) (6) Martin, Stacey
(CDC/DDID/NCEZID/DVBD) [(b) (6) McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD) [(b) (6)]
Goldstein, Jason (CDC/DDID/NCEZID/DSR) [(b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD)
[(b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [(b) (6) Lindsey, Nicole
(CDC/DDID/NCEZID/DVBD) [(b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [(b) (6)]; Wachtel,
Jonathan' (b) (6) Stratton, Benjamin [(b) (6) Margaret Anderson
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[(b) (6) Kathleen Callahan [(b) (6) Molloy, Delia (DPH)
[(b) (6) Wood, Gretchen (NIH/OD) [E] [(b) (6) Filip Dubovsky
[(b) (6)]; Michael Watson (x) [(b) (6) Jacqueline Miller
[(b) (6) Antonio Lanzavecchia [(b) (6) Arvin, Ann
[(b) (6) Harris, Rebecca /SG [Rebecca.Harris@sanofi.com]; Vivek Shinde [(b) (6)
Cohen, Myron [(b) (6) Criffield, Robin R. [(b) (6) Marovich, Mary
(NIH/NIAID) [E] [(b) (6) FNIH [(b) (6) Barton Haynes, M.D.
[barton. (b) (6) Michael, Nelson [(b) (6) Brown ScD, Elizabeth R
[(b) (6) Pettifor, Audrey E [(b) (6) Janes PhD, Holly E (b) (6) ;
Stephenson, Kathryn (HMFP - Vaccine Research) [(b) (6) Najaf Shah [(b) (6)];
Young, John (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: ACTIV Vaccines Working Group meeting

Location: <https://fnih.zoom.us>, (b) (6)

Start: 12/14/2020 5:00:00 PM

End: 12/14/2020 6:00:00 PM

Show Time As: Busy

Required Attendees: Santos, Michael (FNIH) [T]; (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell (b) (6) (b) (6) Cavaleri Marco; (b) (6) (b) (6) Barton; (b) (6) (b) (6) Greg Glenn; (b) (6) Haynes, Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; (OS/ASPR/BARDA); (b) (6) (b) (6) ; Tal Zaks

Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowsk, Mary (NIH/NCI) [C]; Johnson Maureen (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Dieffenbach, Carl (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Elen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; François P Roman; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Martin, Stacey (CDC/DDID/NCEZID/DVBD); McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD); Goldstein, Jason (CDC/DDID/NCEZID/DSR); Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Lindsey, Nicole (CDC/DDID/NCEZID/DVBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; (b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Molloy, Delia (DPH); Wood, Gretchen (NIH/OD) [E]; Filip Dubovsky; Michael Watson (x); Jacqueline Miller; Antonio Lanzavecchia; Ann Arvin; Harris, Rebecca /SG; Vivek Shinde; Cohen, Myron; Criffield, Robin R.; Marovich, Mary (NIH/NIAID) [E]; FNIH; Barton Haynes, M.D.; Nelson Michael; Brown ScD, Elizabeth R; Pettifor, Audrey E; Janes PhD, Holly E; Stephenson, Kathryn (HMFP - Vaccine Research); Najaf Shah

Michael Santos is inviting you to a scheduled Zoom meeting.

Topic: ACTIV Vaccines Working Group meeting

Time: Dec 14, 2020 12:00 PM Eastern Time (US and Canada)

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From: Appell, Evan [(b) (6)]
Sent: 11/5/2020 7:44:52 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)]; Eisner, Mark [(b) (6)]; Gottesd ener, Keith [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa [(b) (6)]; Levy, Elliot [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]; Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6)]; Poole, Mike [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn [(b) (6)]; Garner, Carl [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner

[(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6)]; [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H. Iary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]

Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20201105_vf.pdf

Hi All,

Thank you for attending our TX-Clinical Working Group meeting this afternoon. Please see attached for the materials that we reviewed, and the presentation now also includes two new slides showing the demographic breakdowns for ACTIV-2/3.

Please let us know if you have any questions, and thank you all for your support.

Best,
Evan

Evan Appell
Deloitte Consulting LLP
Mobile (b) (6)

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] <(b) (6)>

Sent: Monday, August 31, 2020 10:34 AM

To: Adam, Stacey (FNIH) [T]; Appell, Evan; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

(b) (6) Sizemore, Christine (NIH/FIC) [E]

Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin, (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia

Subject: ACTIV Therapeutics-Clinical Working Group Meeting

When: Thursday, November 5, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom>. (b) (6)

---Original Appointment---

From: Adam, Stacey (FNIH) [T] <(b) (6)>

Sent: Wednesday, June 17, 2020 8:48 AM

To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]

Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon,

Stratton, Benjamin, (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Occurs every Thursday effective 6/25/2020 until 12/31/2020 from 1:00 PM to 2:00 PM Eastern Standard Time.
Where: <https://fnih.zoom>. (b) (6)

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://fnih.zoom>. (b) (6)

Meeting ID: (b) (6)

Password: (b) (6)

One tap mobile

(b) (6)

US (Germantown)

US (Chicago)

Dial by your location

(b) (6)

US (Germantown)

US (Chicago)

US (New York)

US (Tacoma)

US (Houston)

US (San Jose)

US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

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v.E.1

Sent: 5/15/2020 11:49:33 AM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information
Attachments: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

These list were compiled yesterday morning by FNIH without any names, only emails. I wanted to double check the emails FNIH provided with names of the reps on the 4 ACTIV WGs along with the reps who participated in the April 3rd PPP meeting.

I found 8 emails that were missing and shared this with FC yesterday afternoon. Andy Plump was among the 8 which explains why the email was missing.

From: Myles, Renate (NIH/OD) [E] < (b) (6)>
Sent: Thursday, April 16, 2020 8:15 AM
To: Parker, Ashley (NIH/OD) [E] < (b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E] < (b) (6)>
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

I used the master list that you sent to him earlier in the week and Takeda wasn't in there. I never received an updated version of the master list.

From: Parker, Ashley (NIH/OD) [E] < (b) (6)>
Sent: Thursday, April 16, 2020 8:14 AM
To: Myles, Renate (NIH/OD) [E] < (b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E] < (b) (6)>
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

Here is the updated list -- seems FC used your emails and not the master list.

From: Myles, Renate (NIH/OD) [E] < (b) (6)>
Sent: Thursday, April 16, 2020 8:10 AM
To: Parker, Ashley (NIH/OD) [E] < (b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E]
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

I pulled the names from the attached that you sent earlier in the week. There isn't a Takeda contact on this list. Would you send it to me?

From: Parker, Ashley (NIH/OD) [E] < (b) (6)>
Sent: Thursday, April 16, 2020 8:03 AM
To: Myles, Renate (NIH/OD) [E] < (b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E]
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

Good morning Renate,

Our rep at Takeda, Andy Plump is included on the master list. I am confirming with Francis that he used our master list for his email that went out last night – I should be able to confirm this for you this morning.

I hope you are staying safe and healthy; maybe even getting some rest in between the constant COVID activities.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] (b) (6)
Sent: Thursday, April 16, 2020 7:14 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Subject: FW: PLEASE READ: Draft Email to Collect Communication Contact Information
Importance: High

Hi Ashley:

I'm not sure if Francis added a Takeda contact to his email. I could not find one on the master contact list. I have not heard from their organizations yet. Would you let me know if you provided that to him last night or if they are missing from this email? Need to send it to this group this morning.

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]
Sent: Wednesday, April 15, 2020 9:11 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wood, Gretchen (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E]
(b) (6) Burklow, John (NIH/OD) [E] (b) (6) Parker,
Ashley (NIH/OD) [E] (b) (6)
Subject: PLEASE READ: Draft Email to Collect Communication Contact Information
Importance: High

Hi Francis:

We need to collect the communication contacts from the partner organizations so we can share the release with them for review. Below is 1) a draft email for you to send to the company participants, 2) the contacts for the companies we list in the release except for Takeda (I could not find a Takeda contact on the master list; hoping Ashley can provide); 3) those who should be copied (feel free to add others).

Dear ACTIV colleagues:

As I mentioned earlier today, we would like to announce the plans for a public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at (b) (6) and Abbey Meltzer (b) (6) this evening, if possible.

BCC:

(b) (6)

(b) (6)

CC:

(b) (6)

Thanks,
Renate

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/30/2020 4:52:43 PM
To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: Gilead and ACTIV TX-Clinical Master Protocol Subgroup Meeting #7
Flag: Follow up

Great. Talk to you at 5 then.

From: Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Sent: Thursday, April 30, 2020 12:51 PM
To: Wholley, David (FNIH) [T] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>
Subject: Gilead and ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

I received an email yesterday (prior to the press release) from a relatively senior scientist that Gilead has re-considered and would like to be part of ACTIV. I was going to mention it on the call this afternoon. I think having them as part of ACTIV – given they have a strong track-record and likely the first directly acting anti-viral - would be good.

Cliff

From: "Wholley, David (FNIH) [T]" <(b) (6)>
Date: Thursday, April 30, 2020 at 10:18 AM
To: "Collins, Francis (NIH/OD) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)>
Subject: FW: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

FYI, something to think about.

From: Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>
Sent: Thursday, April 30, 2020 9:19 AM
To: Adam, Stacey (FNIH) [T] <(b) (6)> >; Butterson, Joan <(b) (6)> >, Collins, Sylvia <(b) (6)>
(FDA/CDER) <(b) (6)> Judy Currier <(b) (6)> >; De Claro, R. Angelo (FDA/CDER) <(b) (6)>
(b) (6) Mark Eisner <(b) (6)> Keith Gottesdiener <(b) (6)>
>; Eric Hughes <(b) (6)> >; LaVange, Lisa M <(b) (6)>
Elliott Levy <(b) (6)> Sandeep Menon <(b) (6)> Amanda Peppercorn <(b) (6)>
(b) (6) >; Proshan, Michael (NIH/NIAID) [E] <(b) (6)> >; Read, Sarah <(b) (6)>
(NIH/NIAID) [E] <(b) (6)> >; Amanda Peppercorn <(b) (6)> Price, D'onne <(b) (6)>
(FDA/CDER) <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Shen, Yuan Li <(b) (6)>
(FDA/CDER) <(b) (6)> >; Farley, John (FDA/CDER) <(b) (6)> >; Goff, David (NIH/NHLBI) <(b) (6)>
[E] <(b) (6)> >; Vincent, Michael <(b) (6)> >
Cc: Mary Biggs <(b) (6)> >; Demarcus <(b) (6)> >; Macone, Erin <(b) (6)> >;
Tountas, Karen (FNIH) [T] <(b) (6)> >; Wachtel, Jonathan <(b) (6)> >; Elizabeth Kim <(b) (6)>
<(b) (6)> >; Parker, Ashley (NIH/OD) [E] <(b) (6)> >; Butcher, Tina <(b) (6)>
(b) (6) >; Wholley, David (FNIH) [T] <(b) (6)> >; Melencio, Cheryl (FNIH) [T] <(b) (6)>

< (b) (6) Wung, Peter /US (b) (6) Qashu, Felicia (NIH/OD) [E]
(b) (6) Stratton, Benjamin (b) (6)

Subject: Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Good morning all:

It would seem that our active control arm had been identified. Should we get in the queue with Gilead sooner rather than later - or have we already reached out to them?

S

From: "Adam, Stacey (FNIH) [T]" (b) (6)

Date: Thursday, April 23, 2020 at 8:31:00 PM

To: "Bozzette, Sam (NIH/NCATS) [E]" (b) (6) "Butterton, Joan" (b) (6) >
"Collins, Sylva (FDA/CDER)" < (b) (6) "Judy Currier" < (b) (6) "De Claro, R.
Angelo (FDA/CDER)" < (b) (6) "Mark Eisner" < (b) (6) "Keith Gottesdiener"
(b) (6) "Eric Hughes" (b) (6) , "LaVange, Lisa M"
(b) (6) "Elliott Levy" < (b) (6) "Sandeep Menon" (b) (6) ,
"Amanda Peppercorn" (b) (6) , "Proschan, Michael (NIH/NIAID) [E]"
< (b) (6) "Read, Sarah (NIH/NIAID) [E]" (b) (6) , "Amanda Peppercorn"
(b) (6) , "Price, Dionne (FDA/CDER)" (b) (6) > , "Rubin, Daniel B.
(FDA/CDER)" < (b) (6) > , "Shen, Yuan Li (FDA/CDER)" (b) (6) > , "Farley, John
(FDA/CDER)" < (b) (6) , "Goff, David (NIH/NHLBI) [E]" < (b) (6) "Vincent, Michael"
< (b) (6)
Cc: "Mary Biggs" (b) (6) , "Demarcus" (b) (6) > , "Macone, Erin"
(b) (6) , "Tountas, Karen (FNIH) [T]" (b) (6) , "Wachtel, Jonathan"
< (b) (6) , "Elizabeth Kim" <el (b) (6) "Parker, Ashley (NIH/OD) [E]"
(b) (6) "Butcher, Tina" (b) (6) "Wholley, David (FNIH) [T]"
(b) (6) , "Melencio, Cheryl (FNIH) [T]" (b) (6) > , "Wung, Peter /US"
< (b) (6) "Qashu, Felicia (NIH/OD) [E]" < (b) (6) "Stratton, Benjamin"
(b) (6)

Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

1. Agenda
2. Slides for discussion updated with the decisions from today
3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

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From: Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC]
Sent: 10/21/2020 4:47:11 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];
(b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa];
(b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiena]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
(b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim,
Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi
Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li
[(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Dave Frankowski (b) (6) Baric, Toni C
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188];
Gadbois, El en (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
Mason, Stephen [(b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; (b) (6)

Subject: Re: ACTIV Preclinical full working group

Attachments: 10212020 BioQual Good v Bad Stock Rhesus[1].pptx

ACTIV Preclinical Group –

(b) (4)

(b) (4)

Thanks –

Clint

From: (b) (6)
When: 10:15 AM - 11:00 AM October 21, 2020
Subject: ACTIV Preclinical full working group
Location: <https://fnih.zoom.us> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/11/2020 1:58:00 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Hughes, Eric [(b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras], Patel, Naimish (b) (6)]; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) . Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner (b) (6)

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis], Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [(b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas Smalldon [(b) (6) Stratton, Benjamin [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H.lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]

Subject: Materials for ACTIV Therapeutics-Clinical Working Group Meeting #10

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200611_Final.pdf

Dear ACTIV Therapeutics-Clinical Working Group Members,

Please find attached the slides, which include the agenda for today's meeting.
We are looking forward to speaking with you all today.

In addition, just a reminder for those who might need it/be interested in sharing please find below the link to the agent survey to use for submission of an agent for consideration for prioritization.

Complete Survey Here: [ACTIV COVID-19 Clinical and Preclinical Candidate Compound Portal](#)

Thank again to all for your continued participation in this effort.

Best,
Stacey

Stacey J. Adam, PhD

Director, Cancer
Research Partnerships

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 USARMY MEDCOM WRAIR (USA) [(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange
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 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
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 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso];
 (b) (6) dana carl (b) (6) Bethany Stokes
 [(b) (6) Kathleen Callahan [(b) (6) Molloy, Delia (DPH)
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 [(b) (6) Antonio Lanzavecchia [(b) (6) Arvin, Ann
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Vivek Shinde [(b) (6) Cohen, Myron
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 [(b) (6) Barton Haynes, M.D. [barton. (b) (6) Michael, Nelson
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: ACTIV Vaccines Working Group meeting

Location: <https://fnih.zoom.us/j/> (b) (6)

Start: 12/14/2020 5:00:00 PM

End: 12/14/2020 6:00:00 PM

Show Time As: Tentative

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell
 (b) (6) Cavaleri Marco; (b) (6)
 (b) (6); (b) (6) Greg Glenn; (b) (6) Haynes,
 Barton; (b) (6) .ch; Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
 Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6); Seals, Jonathan
 (OS/ASPR/BARDA); (b) (6); Tal Zaks

Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowsk, Mary (NIH/NCI) [C]; Johnson, Maureen
 (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
 (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,
 Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Dieffenbach, Carl (NIH/NIAID)
 [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, E len (NIH/OD) [E]; Wholley, David (FNIH) [T];
 Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James,
 Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS)
 [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; François P Roman; Hamilton, Holli (OS/ASPR/BARDA);
 Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Martin, Stacey
 (CDC/DDID/NCEZID/DVBD); McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD); Schrag, Stephanie
 (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Lindsey, Nicole (CDC/DDID/NCEZID/DVBD);
 Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson,
 Margaret; (b) (6) dana.carlucci@roseliassociates.com; Bethany Stokes; Kathleen Callahan;
 Molloy, Delia (DPH); Wood, Gretchen (NIH/OD) [E]; Filip Dubovsky; Michael Watson (x); Jacqueline Miller; Antonio
 Lanzavecchia; Ann Arvin; Harris, Rebecca /SG; Vivek Shinde; Cohen, Myron; Criffield, Robin R.; Marovich, Mary
 (NIH/NIAID) [E]; FNIH; Barton Haynes, M.D.; Nelson Michael

Michael Santos is inviting you to a scheduled Zoom meeting.

Topic: ACTIV Vaccines Working Group meeting

Time: Dec 14, 2020 12:00 PM Eastern Time (US and Canada)

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(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin
(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen,
Helen Q [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Connely, Sarah [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk,
Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendon, Jesse (b) (6) Nasr, Hana
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1];
Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; btolman
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e];
Tountas Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
(b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana
(b) (6) Castillejos, Carlos (b) (6) FNIH Central Account
(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfield, Anita
(b) (6) Coan, Amanda (b) (6) Conrad, Patricia (NIH/NIAID) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan
(b) (6) Fuhrer, Nicole (b) (6) Giorgi, Sara [sara.giorgi@ema.europa.eu];
Hoban, Michelle (b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange

CC:

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Ibrdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Krack, Kimberly [kimberly]; (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Lever, Susan [susan. (b) (6) Martin, Melisa [(b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth [bminnich@fredhutch.org]; Perala, Mie [mie.perala@takeda.com]; Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riffin, Mary [(b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togash, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togash m]; Underwood, Nancy [(b) (6) Zottoli, Jessica [Jessica. (b) (6) Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Taji li, Ada (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]

Subject: ACTIV Leadership/EC Call #12

Location: <https://fnih.zoom.us/> (b) (6)

Start: 1/14/2021 3:30:00 PM

End: 1/14/2021 5:00:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane, Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER), Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Doug as (NCI) Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos, FNIH Central Account, Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Ibrdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Schuster,

Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Hughes, Karen (NIH/OD) [E]; Tajalli, Ada (NIH/OD) [E]

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 7/21/2020 1:49:09 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria
I (b) (6)
Subject: RE: ACTIV Preclinical full working group

Dear Rosa,

Can you please forward me the invitations to the preclinical WG subgroup meetings?

Thanks,
Ashley

From: Menetski, Joseph (FNIH) [T] < (b) (6) >
Sent: Friday, July 17, 2020 2:48 PM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Cc: Alvarez, Rosa Maria < (b) (6) >
Subject: RE: ACTIV Preclinical full working group

Sorry Ashley, I will follow up with Rosa to make sure you are always on the list (good list, not bad list 😊)

Joe

From: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Sent: Friday, July 17, 2020 2:43 PM
To: Menetski, Joseph (FNIH) [T] (b) (6) >
Subject: RE: ACTIV Preclinical full working group

Hi Joe,

Following up to let you know I did not receive the calendar invites to the preclinical subgroup meetings. I hope to be included soon.

Thank you,
Ashley

From: Menetski, Joseph (FNIH) [T] (b) (6)
Sent: Wednesday, July 8, 2020 2:51 PM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Subject: RE: ACTIV Preclinical full working group

Will do. I have sent a note to Rosa Alvarez to make sure you are added to the subgroups.

Joe

From: Parker, Ashley (NIH/OD) [E] (b) (6)
Sent: Wednesday, July 8, 2020 1:52 PM

To: Menetski, Joseph (FNIH) [T] <(b) (6)>
Subject: RE: ACTIV Preclinical full working group

Thanks, Joel Can you also please add me to the preclinical subgroup meetings?

Ashley

From: Menetski, Joseph (FNIH) [T] <(b) (6)>
Sent: Wednesday, July 8, 2020 1:50 PM
To: John <(b) (6)>; Hild, Sheri (NIH/OD) [E] <(b) (6)>
<(b) (6)>; Baric, Ralph <(b) (6)>
<(b) (6)> Ottinger, Elizabeth (NIH/NCATS) [E] <(b) (6)> Colvis, Christine
(NIH/NCATS) [E] <(b) (6)> Hewitt, Judith (NIH/NIAID) [E] <(b) (6)> Deming, Damon
(FDA/CDER) <(b) (6)>; Parker, Ashley (NIH/OD) [E]
<(b) (6)> Adams, Peter (OS/ASPR/BARDA)
<(b) (6)>; Rao, Srinivas <(b) (6)> Qashu, Felicia (NIH/OD) [E]
Tomas Cihlar <(b) (6)> Pitt, Margaret L CIV USARMY MEDCOM USAMRIID
(USA) <(b) (6)>; Punturieri, Antonello (NIH/NHLBI) [E] <(b) (6)> Charette, Marc
(NIH/NHLBI) [E] <(b) (6)>; Fessel, Josh (NIH/NHLBI) [E] <(b) (6)>
Cc: Diamond, Michael <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Florence,
Clint (NIH/NIAID) [E] <(b) (6)>; Simon, Dina (NIH/OD) [C] <(b) (6)>; Wholley, David (FNIH)
<(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)>; Colvis, Christine (NIH/NCATS) [E]
>; Desrosiers, Betsy <(b) (6)>; Hughes, Eric
<(b) (6)>; Jansen, Kathrin <(b) (6)>; Kurilla, Michael (NIH/NCATS) [E]
Lowy, Douglas (NCI) <(b) (6)>; Read, Sarah (NIH/NIAID) [E] <(b) (6)>;
Tountas, Karen (FNIH) [T] <(b) (6)>; Santos, Michael (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T]
<(b) (6)>; James, Stephanie (FNIH) [T] <(b) (6)>; Alvarez, Rosa Maria <(b) (6)>
Kim, Elizabeth <(b) (6)>; Tolman, Brett <(b) (6)> Wachtel, Jonathan
<(b) (6)> Prabhavathi Fernandes <(b) (6)>; Rose Li
<(b) (6)> Dana Carluccio <(b) (6)> Lagos, Enrique (NIH/NCATS) [E]
<(b) (6)> Jonson, Samantha (NIH/NCATS) [E] <(b) (6)>; Gonzalez, Nina
<(b) (6)> Burrus-Shaw, Cyndi (NIH/OD) [E] <(b) (6)> Rodriguez, Robin D
<(b) (6)> Dave Frankowski <(b) (6)> Baric, Toni C
<(b) (6)> Lowy, Douglas (NIH/NCI) [E] <(b) (6)> Nancy Haigwood
<(b) (6)> Stratton, Benjamin <(b) (6)>; Gadbois, Ellen (NIH/OD) [E]
>; Anderson, James (NIH/OD) [E] <(b) (6)>

Subject: ACTIV Preclinical full working group

Dear Preclinical Working group and attendees,

I apologize for not providing the minutes from last week's meeting. Here they are for your review.

Sincerely,
Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
<(b) (6)> fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Tountas Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 4/23/2020 1:35:15 PM
To: Bascles, Lionel [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6) Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshov]; Garner, Carlos [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Klote, Mary [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wachtel, Jonathan [(b) (6)], Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)
Subject: Clinical Trial Capacity Working Group Meeting #3 Summary
Attachments: Clinical_Trial_Capacity_Working_Group_Meeting #3_Summary_FINAL.pdf

Dear Clinical Trial Capacity WG Members,

Attached is the summary for the full working group meeting that took place earlier this week (Tuesday, April 21). The next WG meeting is scheduled for tomorrow, Friday, April 24 at 9am EST, during which we will have a discussion about the agent prioritization process with our colleagues from the Therapeutics clinical WG.

Cheers!
Karen

Karen H. Toussaint, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
(b) (6) fnih.org
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From: Mellors, John W [(b) (6)]
Sent: 7/2/2020 1:41:37 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Alvarez, Rosa Maria [(b) (6)]; Rose Li [(b) (6)]; Mark Krystal [(b) (6)]; Prabhavathi Fernandes [(b) (6)]; Diamond, Michael [(b) (6)]; Sanderson, Philip (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee2d44e63f2645708a3beb2ea1b280a1-sandersonpe]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tressler, Randall (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tresslerri]; Eakn, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Young, John [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Dana Carluccio [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Sumit Chanda [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; (b) (6) Draghia Akli, Ruxandra [JRDUS] [(b) (6)]; Hughes, Eric [(b) (6)]; (b) (6) Rich Colonno [(b) (6)]; Fisher, Robert (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=706cb01f58ef4042aecc4de5ab72ec1-Robert.Fish]
CC: Chen, Helen Q. [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; Merritt, Gabriella Marie [(b) (6)]; Romanowski, Jake [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting

Apologies, booked until 7 PM

From: Adam, Stacey (FNIH) [T] [mailto: (b) (6)]
Sent: Wednesday, July 1, 2020 9:00 PM
To: Eric Hughes < (b) (6) >; Read, Sarah (NIH/NIAID) [E] < (b) (6) >; Ruxandra Draghia Akli < (b) (6) >; Mellors, John W < (b) (6) >; Naimish Patel < (b) (6) >; Colvis, Christine (NIH/NCATS) [E] < (b) (6) >; Young, John < (b) (6) >; Stein, Peter

(FDA/CDER) < (b) (6) Poole, Mike < (b) (6) Buchman, Tim
 (OS/ASPR/BARDA) (CTR) < (b) (6) Vincent, Michael < (b) (6) Keith
 Gottesdiener < (b) (6) Elliott Levy < (b) (6) Wung, Peter /US
 < (b) (6) Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) Higgs, Elizabeth
 (NIH/NIAID) [E] < (b) (6) Carlos O Garner < (b) (6) Goff, David (NIH/NHLBI) [E]
 < (b) (6) Alvarez, Rosa Maria < (b) (6) Rose Li
 < (b) (6) Mark Krystal < (b) (6) Prabhavathi Fernandes
 < (b) (6) Diamond, Michael < (b) (6) Sanderson, Philip (NIH/NCATS) [E]
 < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tressler, Randall (NIH/NIAID) [E]
 < (b) (6) (b) (6) Eakin, Ann (NIH/NIAID) [E] < (b) (6) Young,
 John < (b) (6) Mellors, John W < (b) (6) Higgs, Elizabeth (NIH/NIAID) [E]
 < (b) (6) Dana Carluccio < (b) (6) Menetski, Joseph (FNIH) [T]
 < (b) (6) Sumit Chanda < (b) (6) Colvis, Christine (NIH/NCATS) [E]
 < (b) (6) (b) (6) Draghia Akli, Ruxandra [JRDUS] < (b) (6) Hughes,
 Eric < (b) (6) (b) (6) Rich Colonno < (b) (6) Fisher, Robert
 (FDA/OC) < Robert. (b) (6)
Cc: Chen, Helen Q. < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Alvarez, Rosa Maria
 < (b) (6) Salathin, Carla < (b) (6) Merritt, Gabriella Marie
 < (b) (6) Romanowski, Jake < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)
Subject: RE: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting
Importance: High

Dear ACTIV TX-Clinical Agent Prioritization Subgroup and Antiviral Subteam,

While I could not get quorum for the 12-1pm slot for our discussion tomorrow, many of you said you could be available after 3pm. Therefore, could you all let me know if 3-4pm ET tomorrow would work for you to meet?

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

From: Adam, Stacey (FNIH) [T]

Sent: Tuesday, June 30, 2020 10:55 PM

To: Eric Hughes < (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) >; Ruxandra Draghia-
 Akli (b) (6) John Mellors (b) (6) ; Naimish Patel < (b) (6) >; Colvis,
 Christine (NIH/NCATS) [E] (b) (6) >; Young, John < (b) (6) Stein, Peter
 (FDA/CDER) (b) (6) Poole, Mike (b) (6) ; Buchman, Tim
 (OS/ASPR/BARDA) (CTR) < (b) (6) Vincent, Michael (b) (6) ; Keith
 Gottesdiener (b) (6) >; Elliott Levy (b) (6) >; Wung, Peter /US
 (b) (6) >; Koroshetz, Walter (NIH/NINDS) [E] (b) (6) Higgs, Elizabeth
 (NIH/NIAID) [E] < (b) (6) Carlos O Garner (b) (6) Goff, David (NIH/NHLBI) [E]
 < (b) (6)
Cc: Chen, Helen Q. (b) (6) >; Menetski, Joseph (FNIH) [T] (b) (6) ; Alvarez, Rosa Maria
 < (b) (6) Salathin, Carla < (b) (6) > (b) (6) Parker,
 Ashley (NIH/OD) [E] (b) (6) >

Subject: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting

Dear ACTIV TX Clinical Agent Prioritization Subgroup,

We would like to have a meeting on Thursday with this team and the Antiviral review subteam to discuss and finalize the Antiviral Subgroup's selections from this latest Wave of prioritization.

Please let me know if you would be able to attend this meeting from 12-1pm ET.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Me lars, John W (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Proshan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Ste n, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcabc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (N.H/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Sizemore, Chrstine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli,

Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith
 (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364];
 Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];
 Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike
 [(b) (6) Proschan, Michael (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn
 [(b) (6) Garner, Car [(b) (6) Higgs, Elizabeth (NIH/NIAD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter
 (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E]
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner
 [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV
 DTRA RD (USA) [(b) (6) Petrowick, Martha - 0449 - MITLL [(b) (6)
 (b) (6)
 CC: Gonzalez, Nina [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Kurilla,
 Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Melencio, Cheryl (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Tountas, Karen (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Tolman, Brett
 [(b) (6) Alvarez, Rosa [(b) (6) Margaret Anderson
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Stratton, Benjamin
 [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H lary
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q.
 [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Elsaid, Olivia
 [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bafd32930-walkerpl]; Sorosa, Alex David
 [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis, Christine (NIH/NCATS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
 [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
 (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
 Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
 [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
 (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Dana Carluccio
 [dana. (b) (6) Rose Li Central Account [(b) (6) Margaret Anderson
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smal don
 [Lucas.Small don@roseliassociates.com]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; jennifer.j. (b) (6) Mollica, Linda /US
 [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremcl]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerpl]; Bethany Stokes [(b) (6) asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

Attachments: ACTIV TX-Clinical Working Group Meeting Guide 20201029.pdf

Location: <https://fnih.zoom>. (b) (6)

Start: 10/29/2020 5:00:00 PM

End: 10/29/2020 6:00:00 PM

Show Time As: Tentative

Recurrence: (none)

every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Sizemore, Christine (NIH/FIC) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Ak i, Ruxandra; Eisner, Mark, Gottesdiener, Keith, Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John, Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschian, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylvia (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Krchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6)

Optional Attendees: Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin, Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary, Butcher, Tina; Demarcus, Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla, Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio, Rose L Central Account, Margaret Anderson; Lucas Smalldon, Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andre (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia, Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting in 20 minutes.

Thanks,

Stacey

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Find your local number: <https://fnih.zoom.us/> (b) (6)

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/3/2020 9:34:35 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Updated Master email list
Attachments: Master and WG Email List for ACTIV rv06032020.xlsx

Hi Ashley

Here is the spread sheet updated today with David Reese, Tomas Cihlar (who will be attending leadership team meetings for William Lee, Gilead) and Kara Cater added to Industry and master email list. I have also added Tonya Villafana, AstraZeneca to Vaccines Working Group.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: (b) (6) [(b) (6)]
Sent: 6/4/2020 12:10:55 AM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Re: Updated Master email list

Yes, thank you!!

On Jun 3, 2020, at 7:37 PM, Melencio, Cheryl (FNIH) [T] < (b) (6) > wrote:

Is this what you want?

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

<image001.png>

From: Parker, Ashley (NIH/OD) [E] (b) (6)
Sent: Wednesday, June 3, 2020 5:59 PM
To: Melencio, Cheryl (FNIH) [T] < (b) (6) >
Subject: RE: Updated Master email list

Thanks, Cheryl! Can I also have the updated spreadsheet that the FNIH COMMs group has with names and titles? No rush.

From: Melencio, Cheryl (FNIH) [T] < (b) (6) >
Sent: Wednesday, June 3, 2020 5:35 PM
To: Parker, Ashley (NIH/OD) [E] (b) (6)
Subject: Updated Master email list

Hi Ashley

Here is the spread sheet updated today with David Reese, Tomas Cihlar (who will be attending leadership team meetings for William Lee, Gilead) and Kara Cater added to Industry and master email list. I have also added Tonya Villafana, AstraZeneca to Vaccines Working Group.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

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Donate to the FNHI's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

<image001.png>

<ACTIV Working Group Rosters - MASTER.xlsx>

From: Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 7/8/2020 5:49:38 PM
To: (b) (6) (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];
(b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)
Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]
CC: Diamond, Michael [(b) (6) Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Saran (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel,
Jonathan (b) (6) Prabhavathi Fernandes [prabha. (b) (6) Rose Li
[(b) (6) Dana Carluccio [dana.carluccio@roseliassociates.com]; Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel]; Jonson, Samantha
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=Sbbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
(b) (6) ; Dave Frankowski [(b) (6) Baric, Toni C
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; Stratton, Benjamin
[(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

Subject: ACTIV Preclinical full working group

Attachments: 2020-07-01_Precinical_WG Summary F1.docx

Dear Preclinical Working group and attendees,

I apologize for not providing the minutes from last week's meeting. Here they are for your review.

Sincerely,
Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6) fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 5/2/2020 1:44:28 AM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [E] (b) (6) Eisner, Mark [E] (b) (6) Gottesdiener, Keith [E] (b) (6) Hughes, Eric [E] (b) (6) Judy Currier [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [E] (b) (6) LaVange, Lisa [E] (b) (6) Levy, Elliot [E] (b) (6) Mellors, John W [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [E] (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [naimish.patel@sanofi.com]; Peppercorn, Amanda [E] (b) (6) Poole, Mike [E] (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn [E] (b) (6) Garner, Carl [E] (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw];

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [E] (b) (6) Jansen, Kathrin [E] (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [E] (b) (6) Biggs, Mary [E] (b) (6) Butcher, Tina [E] (b) (6) Demarcus [E] (b) (6) Macone, Erin [E] (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [E] (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [E] (b) (6) Tolman, Brett [E] (b) (6) Alvarez, Rosa [E] (b) (6)

Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Stratton, Benjamin (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm], Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

Subject: Follow-up Materials from ACTIV Therapeutics-Clinical Working Group - Meeting #4

Attachments: ACTIV Therapeutics-Clinical WG 30Apr2020 Meeting Guide.pdf; 2020-04-30 TX-Clinica WG Meeting Summary-v2.pdf; ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v3.xlsx

Dear TX-Clinical WG Members,

I know that I say it a lot, but truly, thank you for all that you have done this week. Despite the need to improve processes and the tight timelines, you all have done so much work over the last three weeks! THANK YOU!

In follow-up to yesterday's meeting, please find attached the following materials:

1. The formal meeting summary
2. The slides that were presented (Some members wished to have them again)
3. The Agent Prioritization Scoring Sheet that has both the Triage Record and the Final Compounds that are being scored by the Agent Prioritization Committee. Please keep in mind that the ~170 agents that under went triage, we already whittled down from a list of ~400 compounds that we pulled from public data bases. We will continuously update our list from new sources and refine the information for each wave of prioritization. We will begin with the 400+ each time unless an agent is decided to be unsafe or unsuitable for COVID-19.

As always, please let me know if you have any questions or amendments to the record.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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Sent: 7/31/2020 8:14:58 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: ACTIV Innovation Playbooks for the COVID-19 clinical trial environment

Thanks!

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Friday, July 31, 2020 3:23 PM
To: Brodd, Lauren (NIH/OD) [E] <(b) (6)>
Subject: FW: ACTIV Innovation Playbooks for the COVID-19 clinical trial environment

FYI

From: Tountas, Karen (FNIH) [T] <(b) (6)>
Sent: Friday, July 31, 2020 3:12 PM
To: Bascles, Lionel (b) (6) >; Cohen, Myron (b) (6) >; Corey, Larry <(b) (6)> Victoria Davey <(b) (6)> Desrosiers, Betsy <(b) (6)> Dickens, Jim (NIH/NCATS) [C] (b) (6) ; Doroshov, James (NIH/NCI) [E] (b) (6) ; Garner, Carlos (b) (6) Goff, David (NIH/NHLBI) [E] (b) (6) ; Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Mensah, George (NIH/NHLBI) [E] (b) (6) Nayak, Seema (NIH/NIAID) [E] (b) (6) Payton, Manizhe (NIH/NIAID) [E] (b) (6) Resnansky, Laura (b) (6) >; Sizemore, Christine (NIH/FIC) [E] (b) (6) >; Srinivasan, Badhri <(b) (6)> Stein, Peter (FDA/CDER) (b) (6) ; Takas, Therese <(b) (6)> Vincent, Mike (b) (6) >; Weinmann, Gail (NIH/NHLBI) [E] (b) (6) ; Heaton, Penny <(b) (6)>
Cc: Wachtel, Jonathan (b) (6) >; Adam, Stacey (FNIH) [T] <(b) (6)> >; Anderson, Margaret (b) (6) >; Parker, Ashley (NIH/OD) [E] <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)> >; Gadbois, Ellen (NIH/OD) [E] (b) (6) >; Gonzalez, Nina <(b) (6)> James, Stephanie (FNIH) [T] (b) (6) ; Kenny, Dermot (b) (6) >; Kublin, James <(b) (6)> Menetski, Joseph (FNIH) [T] (b) (6) ; Qashu, Felicia (NIH/OD) [E] (b) (6) ; Santos, Michael (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)>
Subject: ACTIV Innovation Playbooks for the COVID-19 clinical trial environment

Dear Clinical Trial Capacity Working Group Members,

I am pleased to distribute final versions of the five ACTIV Innovation Playbooks (zip file attached)

- eCOA (Electronic Clinical Outcomes Assessments)
- eConsent
- Mobile Nursing
- Remote Source Data Verification (SDV)
- Site Training/Tools

These 'playbooks' are designed specifically to provide high-level guidance for conducting clinical trials in the COVID-19 environment. Each includes practical guidance, considerations, and recommendations, and may include links to useful

websites, documents such as checklists, sample letters and meeting agendas, materials to conduct due diligence activities, procedure manuals, and more, and potential vendor lists, which may not be complete, but are meant as a place to start. The playbooks are provided to you as Microsoft Word documents rather than pdf so that you may easily open and save the unembedded materials to modify and use. Thank you to our academic, NIH, and pharma colleagues for the enormous amount of time and effort given to producing these playbooks and for sharing your knowledge and materials.

Also attached is an Innovations Quick Reference Guide that provides a brief introduction to many other virtual, digital, online technology solutions or innovations that are becoming increasingly relevant in the COVID-19 clinical trial environment. This is not meant to be a comprehensive list of solutions for clinical trials in general, rather these innovations may help with expeditious and efficient clinical trial execution in the COVID-19 environment. Again, thank you to those on the Innovations Sub-WG who put their heads together and came up with this list and the accompanying considerations.

Please share these resources with your teams.

With my very best regards,
Karen

Karen H. Toumtas, PhD
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Sent: 7/8/2020 1:13:47 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m;
(b) (6) Annaliesa. (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathryn [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: RE: ACTIV Preclinical full working group

Hi all,

Please see below for today's agenda. Looking forward to our discussion at 10am.

Agenda Topic	Duration	Facilitator
Debrief from Leadership Meeting	5 mins	John Young
Discuss approach for preclinical development of combination therapies	15 mins	Christine Colvis
Debrief on NHP prioritization strategy updates	10 mins	Jim Anderson, Joe Menetski
Discuss potential plan for genotypic monitoring	10 mins	Tomas Cihlar, Marco Salemi
Sub Group Updates	15 mins	Sub Group Leads
Align on action items and next steps	5 mins	Joe Menetski Rosa Alvarez

Best regards,
Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6) >

Sent: Tuesday, April 14, 2020 6:44 PM

To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E];

(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD)

[E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/N AID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio, Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C], Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski, Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Subject: ACTIV Preclinical full working group
When: Wednesday, July 8, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom> (b) (6)

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To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; D sbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Do sten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, H lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9a9e95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NARS]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Tal ey, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Virgin, [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodcl]; Young, John

(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis], Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes], Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Halett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaal]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolnetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolnetzc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso], Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse (b) (6) Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1], Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; bto man [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan [(b) (6) Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak] CC: Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim], Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel]; Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: ACTIV Leadership Team Call #13

Location: <https://nih.zoom.us/> (b) (6)

Start: 2/17/2021 4:30:00 PM

End: 2/17/2021 6:00:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn, Lane, Cliff (NIH/NIAID) [E]; Lepore, John, Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert, Plump, Andy; Ramoni, Rachel, Reed, John; Reese, David, Rouse, Doris, Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul, Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip, Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Doug as (NCI) Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina, Hawk, Harrison; Mendelson, Jesse, Nasr, Hana, Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Meltzer, Abbey (FNIH) [T]

Optional Attendees: Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Magbie-Robinson, Kim; Simon, Dina (NIH/OD) [C]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara;

Hoban, Michelle; Hoffstetter, Renata (FNIH) [T], Iberdemaj, Varde; Jenkins, Christine S.; Krack, Kimberly; Lever, Susan, Magbie-Robinson, Kim (NIH/OD) [C], Martin, Melisa, McManus, Ayanna (NIH/OD) [E], Minnich, Beth; Peralá, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]

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From: Alvarez, Rosa Maria [(b) (6)]
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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp] (b) (6)
Puntunieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-puntunieria]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Frank.Nestle@sanofi.com; (b) (6)
Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.ema]; (b) (6)
Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6)
Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6)
Adams, Peter (DS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6)
Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6)
Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)
Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6)
Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6)
Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [(b) (6)
Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6)
Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6)
Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d], Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowy]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwood oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: RE: ACTIV Preclinical full working group

Hi all,

Please see below for our agenda for today's meeting. Let us know if you have any questions.

Agenda Topic	Duration	Facilitator
Debrief from sub group meetings (Sub Group leads) <ul style="list-style-type: none"> Data Portal Implementation In vivo strategy BSL 3 /4 Network Implementation 	30 mins	Sam Jonson, Nancy Haigwood, Clint Florence, Liz Ottinger, Judith Hewitt
Debrief on status of the Pandemic Response SOP manuscript submission	10 mins	Kara Carter, Jay Grobler
Align on next steps and owners	10 mins	Joe Menetski, Rosa Alvarez

Regards,
Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6) >

Sent: Tuesday, April 14, 2020 6:44 PM

To: Menetski, Joseph (FNIH) [T]; (b) (6) Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6)

(b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6)
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/N AID) [E], Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E], Rodriguez, Robin D; Dave Frankowski, Baric, Toni C, Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Subject: ACTIV Preclinical full working group
When: Wednesday, June 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom>. (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://fnih.zoom>. (b) (6)

Meeting ID: (b) (6) 54

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US (Tacoma)
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Meeting ID: (b) (6)

Password: (b) (6)

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Sent: 7/9/2020 3:09:20 PM
Subject: FW: website updates for ACTIV

Hi Joe,

I need your opinion for how we describe the preclinical working group charge on the ACTIV website.

Other possibilities:

- As we previously discussed, the charge of the Preclinical WG is listed on the website as: *Create an integrated preclinical framework to evaluate existing drugs and drug candidates that require preclinical evaluation for both repurposing and development of novel therapeutics.*
 - This is still the language listed in the leadership slides, so not sure if this has been “officially” updated with language we would use for the website, but the JAMA paper lists as: The Preclinical Working Group was charged to standardize and share preclinical evaluation resources and methods and accelerate testing of candidate therapies and vaccines to support entry into clinical trials. We can ask Joe Menetsky to confirm – I will write him.
 - Note: there are slight differences in wording between the JAMA paper and the website, although the Preclinical WG varies the most. Let me know if you want to see a comparison for the other WG between the website and JAMA paper.
- Wasn't sure the final decision on this, but Cat Lutz is on preclinical WG, so should Jackson Labs be listed as a nonprofit partner- should this be verified with FNIH before they are added? According to The Jackson Laboratory website: JAX is an independent, 501(c)3 nonprofit biomedical research institution that seeks to...Is Cat Lutz on the leadership team? If not, JAX should not be listed.
 - I can double check my list but I think that is the only other difference between WG members and leadership organizations (aside from academic institutions).

Wanted to get your thoughts on the list so it is organized to go to Renate today depending on the decision about the companies.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] (b) (6)
Sent: Thursday, July 9, 2020 12:54 AM
To: Santos, Michael (FNIH) [T] (b) (6)
Cc: Wholley, David (FNIH) [T]
Subject: Re: Invitation from Francis Collins to join COVID public-private partnership

Hi Mike,

Yes, I raised this a few weeks ago and agree we should add Moderna and Novavax to the list of companies on the website. I can alert our team to get this updated tomorrow and maybe you can alert Abbey/Greta to update on the FNIH website?

The last time I checked, Cheryl was still waiting to hear back from the Novavax rep on the vaccines WG, Gregory Glenn to see if he approved to be listed on the website — have you heard anything?

Also, there's time to think about inviting Tal Zaks or a rep from Moderna to the leadership team meetings but I'll leave that decision to David and the war room!

Thanks,
Ashley

On Jul 8, 2020, at 11:08 PM, Santos, Michael (FNIH) [T] (b) (6) > wrote:

Hi Ashley,

I remember there was some discussion about which organizations are listed on the ACTIV webpage after you raised the question of Moderna and Novavax not being listed, and what the criteria are for that.

Tal Zaks of Moderna is requesting that they be listed (see below). Given that OWS just made a big investment in Novavax, it may make sense to have their participation listed as well, as its absence may be noticed at this point (and like Moderna they have been regular participants in Vaccines meetings).

Although it would lead to some inconsistencies in the principles of who is listed, at this point it might be most straightforward just to add those two companies. What do you think? If there are any other steps, of course I'm happy to help out.

Thanks,
Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Tal Zaks (b) (6)

Sent: Wednesday, July 8, 2020 10:56 PM

To: Santos, Michael (FNIH) [T] (b) (6)

Subject: Re: Invitation from Francis Collins to join COVID public-private partnership

Dear Michael,

I'm following on this email of a while ago, as it has recently been brought to my attention that we (Moderna) are not listed as a participating organization on the ACTIV website, despite having been active participants since you had kindly invited us back in April.

Can you please help me understand whether this is an oversight of communications or some other omission on my part? If so, can I ask how can we correct it? We are proud to be part of this effort.

Thanks!

Tal

From: "Santos, Michael (FNIH) [T]" (b) (6)

Date: Sunday, April 19, 2020 at 1:53 PM

To: Stephane Bancel (b) (6)

Cc: "Mascola, John (NIH/VRC) [E]" (b) (6) . "Tolman, Brett"

(b) (6) >, Tal Zaks < (b) (6)

Subject: RE: Invitation from Francis Collins to join COVID public-private partnership

Dear Stephane,

Thanks much for your quick reply. We're delighted to have Moderna represented in the Working Group.

Tal: We will follow up with additional information and calendar invitations to the Working Group meetings. Please don't hesitate to reach out with any questions. We're looking forward to working with you.

Best regards,
Mike

Michael Santos, PhD

Associate Vice President, Science, Foundation for the National Institutes of Health

From: Stephane Bancel (b) (6) >
Sent: Sunday, April 19, 2020 1:50 PM
To: Santos, Michael (FNIH) [T] (b) (6)
Cc: Mascola, John (NIH/VRC) [E] (b) (6) >; Tolman, Brett (b) (6) ; Tal Zaks (b) (6)
Subject: Re: Invitation from Francis Collins to join COVID public-private partnership

Dear Mike, thanks a lot for the invitation. We appreciate it given our already great partnership with NIAID on the mRNA-1273 clinical development. We are finalizing our Phase 2 plans.

Tal Zaks, our CMO leads our SARS-CoV-2 vaccine development. I think he will be the right person to participate in that group.

He is copied here

Cheers

stephane

From: "Santos, Michael (FNIH) [T]" (b) (6)
Date: Sunday, April 19, 2020 at 12:09 PM
To: Stephane Bancel (b) (6)
Cc: John Mascola (b) (6) , "Tolman, Brett" (b) (6)
Subject: Invitation from Francis Collins to join COVID public-private partnership

Dear Stephane,

If you have not already, you will soon receive an invitation from Francis Collins to join the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, and in particular the Vaccines Working Group, which John Mascola is also a member of.

The next meeting of the Vaccines Working Group is tomorrow (Monday, Apr 20) at 9am ET; a calendar invitation follows. Further information and materials are attached. We hope you will be able to participate. Please do not hesitate to reach out with any questions, and we would be happy to provide additional information.

Best regards,
Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

(b) (6)

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 1/12/2021 9:53:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] (b) (6); Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Victoria Davey [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [(b) (6) Erck, Stan [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Johnson, Robert (OS/ASPR/BARDA) [(b) (6)]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Pandya, Hitesh [hiteshpandya@astrazeneca.com]; Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [(b) (6)]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Woodcock, Janet (FDA/OC) [(b) (6) Young, John [(b) (6) Anderson, James (NIH/OD) [E] [(b) (6)]; Burklow, John (NIH/OD) [E] [(b) (6) Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6) Lumsden, Joanne [(b) (6) Myles, Renate (NIH/OD) [E] [(b) (6) Wolinetz, Carrie [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6)]; Meltzer, Abbey (FNIH) [T] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Margaret Anderson [(b) (6) Appell, Evan [(b) (6) Chen, Helen [(b) (6)]; Connelly, Sarah [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6) Mendelson, Jesse [(b) (6) Nasr, Hana [(b) (6) Sorosa, Alex [(b) (6) Stratton, Benjamin [(b) (6) btolman [(b) (6) Wachtel, Jonathan [(b) (6)], Embry, Alan (NIH/NIAID) [E] [(b) (6) Venkayya, Rajeev [(b) (6) Bancel, Stephane [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pangalos, Mene [(b) (6) Paul, Steve [(b) (6) Rachel Ramoni [(b) (6) Reed, John [(b) (6) Austin, Sarah (NIH/NIAID) [E] [(b) (6) Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Carver, Trea (NIH) [C] [(b) (6) Caulfied, Anita [(b) (6) Coan, Amanda [(b) (6)]; Conrad, Patricia (NIH/NIAID) [E] [(b) (6) gov]; Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6)]; Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [sara. (b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [(b) (6) Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6)], Lever, Susan [(b) (6) Magbie-Robinson, Kim (NIH/OD) [C] [(b) (6) Martin, [(b) (6)

Melisa [(b) (6) McManus, Ayanna (NIH/OD) [E] [(b) (6)]; Minnich, Beth
 (b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann
 (b) (6) Riccobene, Kim [(b) (6) Riffin, Mary [(b) (6)
 Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Sepulveda,
 Dorina (FNIH) [T] [(b) (6) Simon, Dina (NIH/OD) [C] [dina. (b) (6) Suhana, Tina (NIH/VRC)
 [E] [(b) (6) Thomas, Ashley (FDA/CDER) [(b) (6) Wood, Gretchen (NIH/OD)
 [E] [(b) (6) Hughes, Karen (NIH/OD) [E] [(b) (6) Togashi, Mieke (NIH/NCI) [E]
 [(b) (6)]; Underwood, Nancy [(b) (6) Zottoli, Jessica
 [(b) (6) Regan, Donna M [(b) (6) Vessey, Rupert
 [(b) (6)]; Burke, Leslie [(b) (6) John Lepore [(b) (6)
 Lowy, Douglas (NIH/NCI) [E] [(b) (6) Grant, Sarah [(b) (6) Pruitt, Kim
 (NIH/NLM/NCBI) [E] [(b) (6) m.nih.gov]; Sherry, Steve (NIH/NLM/NCBI) [E] [(b) (6) Bell,
 Julie (b) (6)

Subject: *ACTIV Leadership Team Call #14

Attachments: 03.18.21 ACTIV EC and Leadership Team Meeting 20210317 vFinal.pdf; 03.18.21 ACTIV EC and Leadership Team Meeting APPENDIX 20210317 vF.pdf; 2021-02-17 ACTIV Leadership Team and Executive Committee Meeting Summary vF.pdf

Location <https://fnih.zoom.us/> (b) (6)

Start: 3/18/2021 2:30:00 PM

End: 3/18/2021 4:00:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Meltzer, Abbey (FNIH) [T]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachter, Jonathan; Embry, Alan (NIH/NIAID) [E]; Venkayya, Rajeev; (b) (6)

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Ilerdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Togashi, Mieke (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Regan, Donna M; Vessey, Rupert; Burke, Leslie; John Lepore; Lowy, Douglas (NIH/NCI) [E]; Grant, Sarah; Pruitt, Kim (NIH/NLM/NCBI) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]

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From: Connelly, Sarah [(b) (6)]
Sent: 11/24/2020 2:04:18 AM
To: (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.ema], Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; (b) (6) (b) (6) Tomas Cihlar [(b) (6)] Graham, Barney (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=171892ff532b4c208a546e6fc7e87b8a-bgraham]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [(b) (6)] Zahn, Roland [JRDNL] [(b) (6) .com]; Jacqueline Kirchner [(b) (6)] Erica Ollmann Saphire [(b) (6)] Diamond, Michael [(b) (6)]
CC: antoinette baric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]
Subject: RE: Subgroup discussion of prediction of therapy resistance from emerging viral sequence data
Attachments: 2020-11-18_Precinical_WG_Subgroup_Tx-Resistance_Summary_vF.pdf; 20201123_Viral Sequence Tracking and Testing Efforts_vF.pptx

Hi All,

Thank you all for attending our Preclinical subgroup discussion of prediction of therapy resistance from emerging viral sequence data meeting last week. Please see attached for the notes from our discussion, and let us know if you all have any additions or amendments.

Based on the group discussion, the preclinical team has prepared some slides on ongoing viral sequence tracking and testing efforts (attached). On **slides 2 and 3**, you will notice that we have requested input from the subgroup members. **Please take a moment to review these topics** and share any thoughts you may have with myself and Joe. We will consolidate and share the feedback ahead of the next subgroup meeting. We look forward to continuing to develop and refine this effort and appreciate the time and effort you all have put towards this subject to date.

Best Regards,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: (b) (6)
www.deloitte.com

From: Menetski, Joseph (FNIH) [T] < (b) (6) >
Sent: Tuesday, November 17, 2020 8:10 PM

GADB0000001913-2516498

To: (b) (6) Baric, Ralph < (b) (6) Colvis, Christine (NIH/NCATS) [E]
 < (b) (6) (b) (6) (b) (6) Tomas Cihlar
 < (b) (6) Graham, Barney (NIH/VRC) [E] < (b) (6) Hewitt, Judith (NIH/NIAID) [E]
 < (b) (6) Florence, Clint (NIH/NIAID) [E] < (b) (6) Mason, Stephen
 < (b) (6) (b) (6) Zahn, Roland [JRDNL] < (b) (6) Jacqueline
 Kirchner < (b) (6)
Cc: Melencio, Cheryl (FNIH) [T] < (b) (6) Diamond, Michael < (b) (6) Rose Li
 < (b) (6) Dana Carluccio < (b) (6) Baric, Toni C
 < (b) (6) Hawk, Harrison < (b) (6) (b) (6)
 Connelly, Sarah < (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Qashu, Felicia
 (NIH/OD) [E] < (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] < (b) (6) FNIH
 < (b) (6)

Subject: [EXT] Subgroup discussion of prediction of therapy resistance from emerging viral sequence data

Dear all,

Looking forward to our meeting at 10am EST. I am attaching a set of slides for us to talk through and critique, but really am looking forward to the conversation around this important topic.

Best regards,
Joe

Joseph P. Menetski Ph.D.
 Associate Vice President, Research Partnerships
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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 8/20/2020 10:52:05 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: FW: important science and request for action for CoVID-19 Pandemic
Flag: Follow up

Hi Francis,
Please see Mike Santos's response below. I think this would be a very satisfactory response, if you agree. David

From: Santos, Michael (FNIH) [T] < (b) (6) >
Sent: Wednesday, August 19, 2020 10:06 PM
To: Wholley, David (FNIH) [T] < (b) (6) >
Subject: RE: important science and request for action for CoVID-19 Pandemic

Hi David,

Just for the record, contrary to Bob's assertion that this wasn't brought to ACTIV leadership, it was, with the following readout (29 July meeting):

Reviewed concept of using live vaccines to stimulate non-specific immunity to prevent COVID-19

- BCG is the vaccine with the best evidence for non-specific protection, and vaccination with BCG to prevent COVID-19 is being studied in multiple geographies

(Note that Bob was proposing using OPV for those kinds of studies, but the WG did not support that direction.)

I will ask Doug to provide a formal reply to Bob that thanks him again for sharing his ideas with the group and informs him of our perspective (and that we did share it with ACTIV leadership). Doug was instrumental in forming the perspective, so that plus his co-chair role makes him a good messenger. I'll ask him to cc you and Francis on the reply so that you know the loop is closed.

If that sounds good to you, I'm happy to reply to Francis letting him know that's the plan, or for you to do so.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] < (b) (6) >
Sent: Wednesday, August 19, 2020 9:56 PM
To: Wholley, David (FNIH) [T] < (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) >
Subject: FW: important science and request for action for CoVID-19 Pandemic

Seems like some sort of formal response is needed for Dr. Gallo....

From: Gallo, Robert (b) (6)
Sent: Wednesday, August 19, 2020 3:45 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6) <FOV>
Subject: Important science and request for action for CoVID-19 Pandemic

Dear Francis,

I write to you a second time. Knowing that you are a close follower of science information I feel sure you are aware of the weekly increasing evidence strongly favoring our idea of the central role of innate immunity in prevention of infection as well as reducing impact if infection with SARS-COV-2 occurs. As far as I know all studies looking at this favor this point in addition to what we already knew.

I have presented to your committee but they included only the science advisors and no decision makers. As far as I know and actually have been told by members it went well and convincingly so. I was told by some it would be brought forward. However, I have learned that the Executive committee has never hear a word or seen a document or even an email on this. If you have not had an opportunity please do check with the science committee members like Jim Tartaglia, Stan Plotkin, Colonel Nelson Michael, Doug Lowy, and Paul Offit. You know it was favorably received by a site visit from NIH (NIAID to be specific) months ago but not at the top of the Institute for no known reason.

What can the reasons be not to be supportive? I shall compare the 2 approaches. The conventional vaccines inducing lymphoid adaptive immunity versus stimulation of innate immunity.

- 1) The Concepts--The vast majority—almost all the conventional vaccines (of the 170) are based on the use of the spike protein presented in one way or another for delivery with the supposition that they will induce high levels of antibodies to them which will **harmlessly** and **specifically** prevent infection and be **long lasting** (the ultimate like measles “one shot” for a life time).

However, first of all, there is little evidence for safety, particularly if the vaccines do not protect against infection and a bit to be worried about. On that argument we can wait and see. Secondly, and not often thought about, as far as I can see there is no advantage of specificity! Why would anyone be concerned if a vaccine (like OPV) will work against many viruses. Thirdly, and the one and only key argument for the conventional vaccines versus OPV is durability (like measles). In that case and we are fully aware that OPV could not be very long lasting, we looked to OPV as filling a gap until such a conventional vaccine were available. Thus, I was thinking of OPV as a plan A, and we brought this idea forward in February—more than a half year ago. However, with time I see serious possibilities that even if these spike vaccines work the antibody responses will NOT be long lasting. There are several reasons which draw me to that conjecture. I can enumerate them to you or discuss by phone if you wish. They do boil down to the literature and to the very structure of the spike.

- 2) Convenience—OPV is a few drops on the tongue. The Conventional Vaccines based on the spike are chiefly if not solely injections.
- 3) Cost---OPV is 15 cents. What do the spike vaccines cost?
- 4) Availability---there are millions of doses of OPV available now or within a very short time by at least 3 or 4 pharmaceutical companies, and they were available in February when we brought this forward. Compare that to the conventional vaccines which are still in development/production.

- 5) Speed of action once taken (if they work) will require weeks to induce the right and adequate levels of antibodies or killer T cells. Compare that to OPV which works within a few hours thereby likely allowing people to return to work.
- 6) Safety—we have no idea about the long-term safety of these newly developing conventional vaccines, particularly if not protected and the person becomes infected. In contrast BILLIONS of people have received OPV safely, and in a polio virus vaccinated population to my knowledge there is not one example of a bad safety effect.
- 7) Efficacy—do they work? I know of NO DATA of protection in any animal model with the conventional-spike based vaccines. This is very worrisome. In contrast OPV has prevented infection in humans with unrelated viruses like Flu (3.8 fold) resulting in almost 80% protection—better than with Flu vaccines. It will work.

In summary: please consider supporting 2 pilot rapid studies: deliberate infections with unrelated but SAFE viruses, providing very rapid data to prove to you and others in our era that this will work. It could generate answers in a few weeks after beginning. Cost—likely 5 to 10 million.

If you will do it also a field trial involving several Universities ready to begin now—but this would be more expensive—involving preventing infection in high risk groups.

My colleagues and several consultants and I would be happy to discuss this with you in detail in a meeting.

Sincerely yours,

Bob Gallo

From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/14/2020 12:12:53 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [(b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras], Patel, Naimish [naimish.patel@sanofi.com]; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp); James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst); Wachtel, Jonathan
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 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d); Dana Carluccio [(b) (6) Rose
 Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas
 Smaldon [(b) (6) Stratton, Benjamin [(b) (6)
 (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm); Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]

Subject: Materials for ACTIV TX-Clinical Working Group #6

Attachments: FDA Guidance on COVID Trials.pdf; ACTIV Therapeutics-Clinical Full Working Group_14May2020 Meeting Guide.pdf

Dear TX-Clinical Working Group,

Please find attached the slides for tomorrow's call to help facilitate our report outs from both groups. If you have any additions or amendments to propose, please send them to me.

The co-chairs will be updating the group on the ACTIV Executive Committee's feedback and promised actions in response to our letter. This will include some immediate next steps for our group on the mAbs master protocol discussion. Thank you all once again for this feedback to the leadership. It was well received, and it looks like will elicit immediate action on some of the requests.

In addition, please find attached the FDA Guidance for COVID-19 trials that was released today. You can also find it at this link if needed: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-developing-drugs-and-biological-products-treatment-or-prevention>

Looking forward to tomorrow's call.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 6/29/2020 3:24:00 AM

To: Ab Babiker [(b) (6) Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.cabr.um]; Thomas Murray [(b) (6) LaVange, Lisa M [(b) (6) Max Parmar [(b) (6) Birgit Grund [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; David Vock [(b) (6) Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; (b) (6) Ginny Kan [(b) (6) Samuel.Brown@mail.org; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Pau Klekotka [(b) (6) (b) (6) Phillips, Andrew [(b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Roger Paredes (b) (6) ; (b) (6) (b) (6) Shweta Sharma [(b) (6) Moskowitz, Alar (b) (6) (b) (6) Wentworth, Debby [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dc146ea82bb402cb5c6596f43056347-wentw001.um]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Joe Koopmeiners [(b) (6) Gelijns, Annetine [(b) (6) Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; Andrew Phillips [(b) (6) Jens Lundgren (b) (6) (b) (6) Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Baker, Jason [(b) (6) (b) (6) (b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; (b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Ginde, Adit [(b) (6) Mark Polizzotto [(b) (6) Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.cabr]; Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Jim Neaton [(b) (6) Sandeep Menon [(b) (6) Karen Lynn Price [(b) (6) Ajay Nirula [(b) (6) Eric Hughes [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]

CC: Chen, Helen Q. [(b) (6) Demarcus [(b) (6) Bagriella, Emilia [(b) (6) (b) (6) Wachtel, Jonathan (b) (6) Erhardt, William (HHS/IOS) [William. (b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Lisbeth Jørgensen [(b) (6) Daar, Eric [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Eron, Joseph J Jr (b) (6) Chew, Kara M.D. [(b) (6) Harrigan, Rachel (HHS/IOS)

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]

Subject: ACTIV-3 Writing Team
Attachments: ACTIV_TX-Clinical_ACTIV-3 Writing Team Meeting Agenda 20200629.pdf
Location: <https://fnih.zoom>. (b) (6)

Start: 6/29/2020 4:00:00 PM
End: 6/29/2020 5:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Monday from 11:00 AM to 12:00 PM

Required Attendees: Ab Babiker; Neaton, Jim; Thomas Murray, Lisa LaVange; Max Parmar; Birgit Grund; Lane, Cliff (NIH/NIAID) [E]; David Vock; Rachel Harrigan; Aggarwal, Neil (NIH/NHLBI) [E]; (b) (6) Ginny Kan; (b) (6) Phillips, Andrew (b) (6) Read, Sarah (NIH/NIAID) [E]; Paul Klekotka; (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; Roger Paredes; (b) (6) Shweta Sharma; Moskowitz, Alan; Wentworth, Debby; Higgs, Elizabeth (NIH/NIAID) [E]; Joe Koopmeiners; Geijns, Annetine; Erhardt, William (HHS/IOS); Cavan, Reilly; Andrew Phillips; Jens Lundgren; (b) (6) Kozak, Marina (OS/ASPR/BARDA); Baker, Jason; (b) (6) Judy Currier; Miller, Marissa A (NIH/NHLBI) [E]; (b) (6) Patterson, Amy (NIH/NHLBI) [E]; Ginde, Adit; Mark Polizzotto; Denning, Eileen; Proschan, Michael (NIH/NIAID) [E]; Jim Neaton; Sandeep Menon; Karen Lynn Price; (b) (6) Ajay Nirula, Eric Hughes; Reineck, Lora (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Demarcus; Bagiella, Emilia; (b) (6) (b) (6) Wachtel, Jonathan; Erhardt, William (HHS/IOS); Tountas, Karen (FNIH) [T]; Lisbeth Jørgensen Daar, Eric; Parker, Ashley (NIH/OD) [E]; Eron, Joseph J Jr; Chew, Kara M.D.; Harrigan, Rachel (HHS/IOS)

Dear ACTIV-3 Writing Team,

Please find attached a high level agenda for tomorrow's call from 12-1pm ET.

Thanks,
Stacey

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 7/15/2020 5:51:01 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: ACTIV Vaccines Working Group meeting
Location: Webex: <https://nih.webex.co> (b) (6)
Start: 7/29/2020 2:00:00 PM
End: 7/29/2020 3:00:00 PM
Show Time As: Tentative

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell
(b) (6) rg; Cavaleri Marco; (b) (6)
mmdavis@stanford.edu; (b) (6) Greg Glenn; (b) (6) Haynes,
Barton; (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan
(OS/ASPR/BARDA); (b) (6) tonya.villafana@astrazeneca.com; Tal Zaks; Collins, Francis (NIH/OD)
[E]
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowsk, Mary (NIH/NCI) [C]; Johnson, Maureen
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,
Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];
Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melendio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];
Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];
Desrosiers, Betsy, Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul
Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil;
Schrage, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie
(CDC/DDID/NCIRD/DVD), Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;
(b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Arvin, Ann;
Wood, Gretchen (NIH/OD) [E]

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/8/2020 4:28:42 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Marks, Peter (FDA/CBER) [(b) (6) Pao, William [(b) (6) Plump, Andrew [(b) (6) Stoffels, Paul [(b) (6)]; Woodcock, Janet (FDA/CDER) [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathryn [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6)]; Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Young, John [(b) (6)]
CC: Adam, Stacey (FNIH) [T] [(b) (6) Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Chen, Helen [(b) (6) Elsaid, Olivia [(b) (6) Gonzalez, Nina [(b) (6) James, Stephanie (FNIH) [T] [(b) (6)]; Menetski, Joseph (FNIH) [T] [(b) (6)]; Santos, Michael (FNIH) [T] [(b) (6) Stratton, Ben [(b) (6) Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [(b) (6)]; Dimishkov, Roxanne [(b) (6) McManus, Ayanna (NIH/OD) [E] [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Thomas, Ashley (FDA/CDER) [(b) (6) Wood, Gretchen (NIH/OD) [E] [(b) (6) Togashi, Mieko (NIH/NCI) [E] [(b) (6) Zottoli, Jessica [(b) (6) Sepulveda, Dorina (FNIH) [T] [(b) (6) Burklow, John (NIH/OD) [E] [(b) (6)]; Gorman, Greta (FNIH) [T] [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6)]; Meltzer, Abbey (FNIH) [T] [(b) (6) Myles, Renate (NIH/OD) [E] [(b) (6) Wolinetz, Carrie (NIH/OD) [E] [(b) (6) Anderson, James (NIH/OD) [E] [(b) (6) Austin, Christopher (NIH/NCATS) [E] [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6)]; Lane, Cliff (NIH/NIAID) [E] [(b) (6)]; Parker, Ashley (NIH/OD) [E] [(b) (6)]; Tabak, Lawrence (NIH/OD) [E] [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6)]; Carver, Trea (NIH) [C] [trea. (b) (6) Hardesty, Rebecca (NIH/OD) [C] [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Castillejos, Carlos [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6)]
 FNIH Central Account [(b) (6) Lucas Smalldon [(b) (6)]
 Gadbois, El en (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: ACTIV EC & Working Group Co-Chair Meeting
Location: <https://fnih.zoom.us/> (b) (6)

Start: 7/15/2020 7:00:00 PM
End: 7/15/2020 8:30:00 PM
Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathryn; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John
Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz,

Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Zottoli, Jessica; Sepulveda, Dorina (FNIH) [T]; Burklow, John (NIH/OD) [E]; Gorman, Greta (FNIH) [T]; Hallett, Adrienne (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Culp, Michele (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Burrus-Shaw, Cynd (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Castillejos, Carlos; Lowy, Douglas (NIH/NCI) [E]; FNIH Central Account; Lucas Smalldon

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From: Kayvon Modjarrad [(b) (6)]
Sent: 7/23/2020 9:50:45 PM
To: Tolman, Brett [(b) (6)]; Lowy, Douglas (NIH/NCI) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd];
(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell
(b) (6) [(b) (6)] (b) (6) Cavalieri Marco
[(b) (6)] (b) (6) Greg Glenn [(b) (6)] (b) (6) Haynes,
Barton [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc], (b) (6)
(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John
(NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy
(CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fde4598a57b423d484dcf9f-offit.email] (b) (6)
Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se];
(b) (6) tonya.villafana@astrazeneca.com; Tal Zaks [(b) (6)]
(b) (6) Greg Glenn [(b) (6)] Gruber,
Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda],
(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com]
CC: (b) (6) Hopps, Markay [(b) (6)] Santos, Michael (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Kozlowski, Mary (NIH/NCI)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen
(NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr];
(b) (6) Jeneffer Haynes (b) (6) (b) (6)
(b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj];
(b) (6) Isabel Ramsey [(b) (6)] Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Henry
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
 [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
 (b) (6) Paul Gillard [(b) (6) Hamilton, Holli (OS/ASPR/BARDA)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; Modjarrad, Kayvon CIV
 USARMY MEDCOM WRAIR (USA) [(b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 Wachtel, Jonathan [(b) (6) Stratton, Benjamin [(b) (6) Anderson, Margaret
 [(b) (6) (b) (6) : (b) (6) Bethany Stokes
 [(b) (6) Kathleen Callahan [(b) (6) Molloy, Delia (DPH)
 [(b) (6) Jacqueline Miller [(b) (6)

Subject: Re: Action: Review Vaccine-associated Enhanced Disease Manuscript
Attachments: COVID - 19 Vaccine Development - VAED DRAFT 7.23.2020_KM.docx

Please find my edits and comments on the latest version attached.

Respectfully,

Kayvon Modjarrad, M.D., Ph.D.
 Director, Emerging Infectious Diseases Branch
 Walter Reed Army Institute of Research
 Medical Officer, Department of the Army
 O1 (b) (6)
 M1
 E1 (b) (6) / E2 (b) (6)

From: Tolman, Brett < (b) (6) >
Sent: Wednesday, July 22, 2020 5:09 PM
To: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell
 (b) (6) (b) (6) Cavaleri Marco; (b) (6) (b) (6)
 (b) (6) Greg Glenn; (b) (6) Haynes, Barton; (b) (6)
 (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy
 (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan (OS/ASPR/BARDA),
 (b) (6) (b) (6) Tal Zaks; (b) (6)

< (b) (6) Wholley, David (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T]
 < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6)
 Tountas, Karen (FNIH) [T] < (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Colvis, Christine
 (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy < (b) (6) Eric Hughes
 < (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Read, Sarah (NIH/NIAID) [E]
 < (b) (6) Young, John < (b) (6) Paul Gillard < (b) (6) Hamilton,
 Holli (OS/ASPR/BARDA) < (b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)
 < (b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) < (b) (6) Verani, Jennifer R.
 (CDC/DDID/NCIRD/DBD) < (b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) < (b) (6) Gonzalez,
 Nina < (b) (6) Wachtel, Jonathan < (b) (6) Stratton, Benjamin
 < (b) (6) Anderson, Margaret < (b) (6) (b) (6)
 (b) (6) Bethany Stokes < (b) (6) Kathleen Callahan
 < (b) (6) Molloy, Delia (DPH) < (b) (6) Jacqueline Miller
 < (b) (6) Kayvon Modjarrad < (b) (6)

Subject: Action: Review Vaccine-associated Enhanced Disease Manuscript

Dear Vaccines Working Group and Sub-Group Members,

Thanks to everyone who provided input on the previous version of the vaccine-associated enhanced disease manuscript that we shared. The authors have incorporated your feedback and made additional improvements. We are nearing submission to Science Translational Medicine, which has indicated interest.

Because the article is a product of the Working Group, we would appreciate your final review. **Could you kindly take a look at the manuscript and provide any feedback or comments you may have by Thursday, July 22 at 8 PM ET?**

Thank you for your help and we are excited to be nearing submission!

Sincerely,

Brett & Mike

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Sent: 8/7/2020 4:49:43 PM

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(b) (6) Lowy, Douglas (NIH/NCI) [E] (b) (6) (b) (6)

Arvin, Ann (b) (6) Beth Bell (b) (6) (b) (6) (b) (6)

(b) (6) Cavaleri Marco (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) Greg Glenn (b) (6) (b) (6)

(b) (6) Haynes, Barton (b) (6) (b) (6) (b) (6)

Marks, Peter (FDA/CBER) (b) (6) Mascola, John (NIH/VRC) [E] (b) (6) Nelson Michael (nelson. (b) (6) Offit, Paul (b) (6) (b) (6) Seals, Jonathan (OS/ASPR/BARDA) (b) (6) (b) (6) (b) (6)

Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Tal Zaks [Tal. (b) (6)

CC: Tolman, Brett (b) (6) (b) (6) Hopps, Markay (b) (6)

Kozlowski, Mary (NIH/NCI) [C] [mary.kozlowski@nih.gov]; Johnson, Maureen (NIH/NCI) [E] (b) (6) .gov]; (b) (6) Jeneffer Haynes (b) (6)

(b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] (b) (6)

(b) (6) (b) (6) Isabel Ramsey (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hi ary (NIH/NIAID) [E] (b) (6) Qashu, Felicia (NIH/OD) [E] (b) (6) Culp, Michel e (NIH/OD) [E] (b) (6) Gadbois, Ellen (NIH/OD) [E] [gadboisel@od.nih.gov]; Wholley, David (FNIH) [T] (b) (6) Melencio, Cheryl (FNIH) [T] (b) (6) Menetski, Joseph (FNIH) [T] (b) (6) Adam, Stacey (FNIH) [T] (b) (6) Tountas, Karen (FNIH) [T] (b) (6)

James, Stephanie (FNIH) [T] (b) (6) Colvis, Christine (NIH/NCATS) [E] [christine.colvis@nih.gov]; Desrosiers, Betsy (b) (6) Eric Hughes (b) (6) Kurilla, Michael (NIH/NCATS) [E] (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) Paul Gillard (b) (6) François P Roman (b) (6) Hamilton, Holli (OS/ASPR/BARDA) (b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) [kayvon.modjarrad. (b) (6) Kathleen Neuzil (b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) (b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) (b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) (b) (6) 'Wachtel, Jonathan' (b) (6)

Stratton, Benjamin (b) (6) (b) (6) (b) (6)

Bethany Stokes (b) (6) Kathleen Callahan (b) (6) Wood, Gretchen (NIH/OD) [E] (b) (6) Filip Dubovsky (b) (6) Arvin, Ann (b) (6) Michael Watson (x) (b) (6) Young, John (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Anderson, Margaret (b) (6)]

Subject: ACTIV Vaccines Working Group meeting

Location: Webex: <https://nih.webex.com/n> (b) (6)

Start: 8/14/2020 5:00:00 PM

End: 8/14/2020 6:00:00 PM

Show Time As: Busy

Required Attendees: Santos, Michael (FNIH) [T]; (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6)

Arvin, Ann; Beth Bell (bzb@bell.com); (b) (6) Cavaleri Marco; (b) (6)

(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes, Barton; (b) (6) (b) (6)

Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) .com; Seals, Jonathan (OS/ASPR/BARDA); (b) (6) (b) (6) Tal Zaks

Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowsk , Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) kel (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E], Qashu, Felicia (NIH/OD) [E]; Culp, M chelle (NIH/OD) [E], Gadbois, El en (N H/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T], James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric; Kunlla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; François P Roman; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; (b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Wood, Gretchen (NIH/OD) [E]; Filip Dubovsky; Ann Arvin; Michael Watson (x)

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From: Tountas Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]

Sent: 6/25/2020 1:38:05 PM

To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Cohen, Myron [(b) (6) Corey, Larry [(b) (6) Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [(b) (6)]; Doroshow, James (NIH/NCI) [E] [(b) (6) Garner, Carlos [(b) (6) Goff, David (NIH/NHLBI) [E] [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Mensah, George (NIH/NHLBI) [E] [(b) (6) Nayak, Seema (NIH/NIAID) [E] [(b) (6)]; Payton, Manizhe (NIH/NIAID) [E] [(b) (6) Resnansky, Laura [(b) (6) Sizemore, Christine (NIH/FIC) [E] [(b) (6)]; Stein, Peter (FDA/CDER) [(b) (6) Takas, Therese [(b) (6) Vincent, Mike [(b) (6) Weinmann, Gail (NIH/NHLBI) [E] [(b) (6)]; Stratton, Ben [(b) (6) Bascles, Lionel [(b) (6) Davey, Victoria [(b) (6) Srinivasan, Badhri [(b) (6) Wachtel, Jonathan [(b) (6)], Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [(b) (6)]; Young, John [(b) (6) Ardiffe, Bernadette [(b) (6) Bernadette. [(b) (6) Criffield, Robin [(b) (6) Hamilton, Nancy [(b) (6) Minnich, Beth [(b) (6) Mueller-Reichenstein, Petra [(b) (6) Pico, Dianna [(b) (6) Quadros, Nora [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [(b) (6) Hill, Zoe (NIH/NHLBI) [C] [(b) (6)]; Adam, Stacey (FNIH) [T] [(b) (6) Anderson, Margaret [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Carluccio, Dana [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6)]; Gadbois, Ellen [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gonzalez, Nina [n.gonzalez@de-ottte.com]; Heaton, Penny [penny. (b) (6) James, Stephanie (FNIH) [T] [(b) (6) Kenny, Dermot [(b) (6) Kublin, James [(b) (6) Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Tuveson, Nancy [(b) (6) Wholley, David (FNIH) [T] [dwhol (b) (6) Elsaid, Olivia [(b) (6) m]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Attachments: Clinical Trial Capacity Working Group Meeting Agenda 07142020 pdf

Location: <https://fnih.zoom.us/> (b) (6)

Start: 7/14/2020 1:00:00 PM

End: 7/14/2020 2:00:00 PM

Show Time As: Tentative

Required Attendees: Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manizhe; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Takas, Therese; Vincent, Mike; Weinmann, Gail; Stratton, Ben

Optional Attendees: Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Ardiffe, Bernadette; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] [(b) (6) Zoe (NIH/NHLBI) Hill [C] [(b) (6) Adam Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] [(b) (6) Carluccio, Dana; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Kenny, Dermot; Kublin, James; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Elsaid, Olivia

Dear WG members; During this call we will share some exciting updates regarding the development of the 'playbooks'; and we will have an important discussion about updating the site survey for NCATS. Looking forward to the call and hope you can make it! Karen

Dear Clinical Trial Capacity Working group members - As the tiger teams continue to work closely with ACTIV protocol development and operations teams, and the 'playbook' development teams ramp up to quickly develop these resources, we will reduce the number of times the full WG meets in July to every other week (July 14th and 28th). Best, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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Password: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 8/2/2020 3:01:00 PM
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(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell
(b) (6) [(b) (6) (b) (6) (b) (6) Cavaleri Marco
[(b) (6) (b) (6) (b) (6) (b) (6) Haynes,
Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002 mc]; hotez@bcm.edu;
(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John
(NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier Nancy
(CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fde4598a57b423d484dcf9f-offit.email], (b) (6)
Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se];
(b) (6) (b) (6) Tal Zaks [(b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) Hopps, Markay [(b) (6)
Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen
(NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr];
(b) (6) Jeneffer Haynes (b) (6) (b) (6)
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hi ary
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD)
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Subject: Notes from the Vaccines Working Group meeting

Attachments: 2020-07-29 Vaccines Working Group meeting Summary Notes.docx

Dear Vaccines Working Group members,

As described in the agenda email (below), we discussed the evolution of the Vaccines Working Group at our last meeting. Please see the attached notes for a summary of the topics proposed as ongoing and future priorities for the group.

In addition, please note that the current plans for future meetings within the Working Group are:

- Vaccines Working Group: to meet as needed, determined by Kathrin and Doug (and potentially at the request of ACTIV Leadership).
- Vaccines Clinical Trials Sub-Group: to meet every other week.
- Other Sub-Groups: Not planning to meet beyond completing existing priorities, such as the vaccine-associated enhanced disease article and summary.

And one related update since the meeting: the vaccine-associated enhanced disease manuscript has been submitted; our gratitude to this group for your input, and our congratulations to the authors and especially Ann and Bart for leading this impressive contribution to this milestone.

Please reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, July 28, 2020 2:58 PM
Subject: Agenda for tomorrow's (Wednesday's) Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Wednesday) at 10am ET / 7am PT / 4pm CEST.

This week is the 16th of the Vaccines Working Group, and Francis Collins will join the start of tomorrow's meeting to recognize the progress we have made. Additionally, we have been asked by ACTIV leadership to consider how the Working Group should operate from here.

We are deeply grateful to all of you for your engagement in our collective efforts. We have identified and addressed many important topics for COVID-19 vaccine development and we have additional contributions yet to come, such as the article on vaccine associated enhanced disease.

At this meeting we would like to discuss the topics that the group would prioritize going forward. We want to support the Working Group to continue to take on issues where we have unique value to add while adjusting the number and frequency of meetings to ensure we are being efficient with everyone's time.

Please come to the meeting with your perspective on what topics are important for the Working Group to address; in the immediate term we plan to continue conversations about the implications of the first vaccine success and of course continue with the dissemination of the vaccine-associated enhanced disease findings. **If you are unable to attend the meeting, as always your thoughts are welcome via email.**

Finally, we want to acknowledge and apologize for the overlap of tomorrow's meeting with the start of the [ACIP meeting](#). We know some of you are directly involved with ACIP and will miss the Working Group meeting. Certainly we will wrap up as soon as our discussion is finished for those who would like to hop over to the ACIP meeting afterwards.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Saturday, July 25, 2020 5:01 PM
Subject: Notes from the Vaccines Working Group meeting

Dear Vaccines Working Group members,

Thank you for your participation in the meeting. The meeting notes and materials are attached.

We're also grateful for the feedback you have provided on the vaccine-associated enhanced disease manuscript. Ann and Bart are working through that now, and we look forward to submitting the final version soon.

We will be in touch again soon about this week's meeting (Wednesday, 10am ET), and in the meantime please feel free to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, July 21, 2020 10:05 PM
Subject: Agenda for the Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our meeting tomorrow (Wednesday), at 1:30pm ET (10:30am PT / 7:30pm CEST).

The agenda topics are:

- Brief update on the vaccine-associated enhanced disease manuscript
 - As a reminder, this is a product of the Working Group and all Working Group members are invited to provide feedback by Thursday at 8pm ET (see attached email sent by Brett on Monday)
- Follow-up discussion of approaches for non-specific immunity
 - Doug will lead this discussion. If you missed the discussion at last week's meeting, the notes are attached again.

As always, please let us know if you have any questions or input.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Sunday, July 19, 2020 4:04 PM
Subject: Notes from the Vaccines Working Group meeting

Dear Vaccines Working Group members,

Thank you for your participation in our last meeting, and particular thanks to Bob Gallo and Konstantin Chumakov and Paula for their presentations and discussion. Attached are the notes and slides presented.

As always, please don't hesitate to reach out with any comments or questions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Friday, July 10, 2020 11:28 PM
Subject: Agenda for the Vaccines Working Group meeting Monday

Dear Vaccines Working Group members,

We're looking forward to our next meeting, Monday at 12pm ET (9am PT / 6pm CEST). There are two agenda topics for the meeting:

- The potential for OPV to provide temporary protection against COVID-19
 - Bob Gallo and colleagues will join to discuss their concept with the group

- A recap of the discussion Thursday in the Vaccines Clinical Trials Sub-Group meeting on the implications of the first vaccine licensure on other vaccine efficacy trials

As inputs to those conversations, the notes from the Clinical Trials Sub-Group meeting are attached along with two press articles and a compendium of journal articles about the OPV concept.

Please don't hesitate to reach out with any questions or feedback.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
(b) (6) fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 11/13/2020 1:35:19 PM
To: Garner, Carl [(b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV

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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e];
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 CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
 (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

Subject: Canceled: ACTIV Therapeutics-Clinical Working Group Meeting
Location: <https://fnih.zoom.us/> (b) (6)

Start: 12/3/2020 6:00:00 PM
End: 12/3/2020 7:00:00 PM
Show Time As: Free

Recurrence: Weekly

every Thursday from 1:00 PM to 2:00 PM

Required

Attendees:

Garner, Carl; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith, Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda, Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylvia (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6)
Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;
(b) (6) Sizemore, Christine (NIH/FIC) [E]

Optional

Attendees:

Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathryn; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Doug as (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose L. Central Account; Margaret Anderson; Lucas Smalldon; Stratton, Benjamin (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David

Dear ACTIV TX-Clinical WG,

Per my email on the NIAID Symposium, we will be cancelling this occurrence the WG to allow for attendance there.

Thanks,
Stacey

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Password: (b) (6)

Find your local number: <https://fnih.zoom>. (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 9/14/2020 7:46:57 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) : Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc8c847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Philips, L Revell CIV DTRA RD (USA) | (b) (6) Petrovick, Martha - 0449 - MITLL | (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7248415bb86087d08b628e6f-melencio]; Salathin, Carla | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio | (b) (6) Rose Li Central Account | (b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]. Lucas Smalldon [Lucas.Smallldon@roseliassociates.com]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c289105913411a3ed28f929042aad-RUBIND.fda]; Marston, H Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) | (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bcfd32930-walkerp1]

Subject: Summary from ACTIV Therapeutics-Clinical Working Group Meeting 09/10/2020

Attachments: 2020-09-10 TX-Clinical WG Meeting_Summary.pdf

Dear ACTIV TX-Clinical WG,

Please find attached the summary from last week's meeting. I hear the discussions went well! Please let us know if you have any additions or amendments to the summary.

Best,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) | Mobile: (b) (6)
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNHI's Pandemic Response Fund to combat COVID-19. fnih.org/pandemic



Sent: 6/19/2020 12:14:28 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: FW: Action items from 6/17/20 ACTIV Executive Committee Teleconference
Attachments: 6.17.20 ACTIV Executive Committee Meeting Action Items vF.docx

From: Wholley, David (FNIH) [T] < (b) (6) >

Sent: Thursday, June 18, 2020 9:33 PM

To: Melencio, Cheryl (FNIH) [T] < (b) (6) > Collins, Francis (NIH/OD) [E] < (b) (6) > Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) > Dolsten, Mikael < (b) (6) > Fauci, Anthony (NIH/NIAID) [E] < (b) (6) > Gibbons, Gary (NIH/NHLBI) [E] < (b) (6) > Marks, Peter (FDA/CBER) < (b) (6) > Pao, William < (b) (6) > Plump, Andrew < (b) (6) > Stoffels, Paul < (b) (6) > Woodcock, Janet (FDA/CDER) < (b) (6) > Colvis, Christine (NIH/NCATS) [E] < (b) (6) > Desrosiers, Betsy < (b) (6) > Hughes, Eric < (b) (6) > Jansen, Kathrin < (b) (6) > Kurilla, Michael (NIH/NCATS) [E] < (b) (6) > Lowy, Douglas (NCI) < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Young, John < (b) (6) > Anderson, James (NIH/OD) [E] < (b) (6) > Austin, Christopher (NIH/NCATS) [E] < (b) (6) > Burklow, John (NIH/OD) [E] < (b) (6) > Culp, Michelle (NIH/OD) [E] < (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) > Hallett, Adrienne (NIH/OD) [E] < (b) (6) > Lane, Cliff (NIH/NIAID) [E] < (b) (6) > Myles, Renate (NIH/OD) [E] < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Tabak, Lawrence (NIH/OD) [E] < (b) (6) > Wolinetz, Carrie (NIH/OD) [E] < (b) (6) > Gadbois, Ellen (NIH/OD) [E] < (b) (6) >
Cc: Adam, Stacey (FNIH) [T] < (b) (6) > Alvarez, Rosa < (b) (6) > Anderson, Margaret < (b) (6) > Chen, Helen < (b) (6) > Elsaid, Olivia < (b) (6) > Gonzalez, Nina < (b) (6) > James, Stephanie (FNIH) [T] < (b) (6) > Kim, Elizabeth < (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Stratton, Ben < (b) (6) > Tolman, Brett < (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) > Wachtel, Jonathan < (b) (6) > Barasch, Kimberly (NIH/NIAID) [C] < (b) (6) > Conrad, Patricia (NIH/NIAID) [E] < (b) (6) > Dimishkov, Roxanne (NIH/NHLBI) [C] < (b) (6) > McManus, Ayanna (NIH/OD) [E] < (b) (6) > Perala, Mie < (b) (6) > Protasiewicz, Ann < (b) (6) > Riccobene, Kim < (b) (6) > Thomas, Ashley (FDA/CDER) < (b) (6) > Wood, Gretchen (NIH/OD) [E] < (b) (6) > Togashi, Mieko (NIH/NCI) [E] < (b) (6) > Zottoli, Jessica < (b) (6) > Lowy, Douglas (NIH/NCI) [E] < (b) (6) > Lucas Smalldon < (b) (6) >

Subject: Action items from 6/17/20 ACTIV Executive Committee Teleconference

Importance: High

Please see attached the action items from yesterday's ACTIV EC meeting. Please let me know any omissions or corrections. Thanks, David

Sent: 5/15/2020 12:57:02 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Al en-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-al engiffor]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Renate,

I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking and was added later on yesterday.

We can send follow up emails to everyone except for those three – they will need to be contacted. Moving forward, it may be best for you to receive updates from the communications team – FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health
(b) (6)

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration
(b) (6)

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International
(b) (6)

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.
(b) (6)

Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory
(b) (6)

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

(b) (6)

Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

(b) (6) ii

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

(b) (6)

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

(b) (6)

Frank Stegmeier, Ph.D.

Chief Scientific Officer
KSQ Therapeutics

(b) (6)

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

(b) (6)

Judith Currier, M.D.

Professor of Medicine
University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)

(b) (6)

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

(b) (6)

Elliot Levy, M.D.

Senior Vice President, Global Development
Amgen

(b) (6)

Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi

(b) (6)

Carlos Garner, Ph.D.
Vice President, Global Regulatory Affairs
Eli Lilly and Company
(b) (6)

Peter Stein, M.D.
Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
(b) (6)

Beth Bell, M.D., MPH
Clinical Professor, Global Health
University of Washington
(b) (6)

Emilio Emini, Ph.D.
Director, TB & HIV Program
Bill & Melinda Gates Foundation
(b) (6)

Kathrin Jansen, Ph.D.
Senior Vice President and Head of Vaccine Research and Development
Pfizer
(b) (6)

Antonio Lanzavecchia, M.D.
Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland
(b) (6)

Nancy Messonnier, M.D.
Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
(b) (6)

Jonathan Seals, Ph.D.
Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority
(b) (6)

From: Myles, Renate (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 15, 2020 7:53 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Allen-Gifford, Patricia (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Wooldridge, Shannon (NIH/OD) [E] <(b) (6)> Pollock, Rachel (NIH/OD)
[E] <(b) (6)>
Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Francis:

Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have Hoping Ashley can provide the missing emails.

(b) (6)

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.

Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

Frank Stegmeier, Ph.D.

Chief Scientific Officer
KSQ Therapeutics

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

Judith Currier, M.D.

Professor of Medicine
University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)

(b) (6)

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

(b)

(c)

Elliot Levy, M.D.

Senior Vice President, Global Development
Amgen

(b) (6)

Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi

(b) (6)

Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs
Eli Lilly and Company

(b) (6)

Peter Stein, M.D.

Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

(b) (6)

Beth Bell, M.D., MPH

Clinical Professor, Global Health
University of Washington

Emilio Emini, Ph.D.

Director, TB & HIV Program
Bill & Melinda Gates Foundation

(b) (6)

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

(b) (6)

Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow

Vir Biotechnology, Inc.

Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

(b) (6)

Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

(b) (6)

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology

Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] (b) (6) >

Cc: Myles, Renate (NIH/OD) [E] <(b) (6)>; Meltzer, Abbey (FNIH) [T] (b) (6) Wholley, David (FNIH) [T] (b) (6)

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];
 (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] [(b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
 (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
 (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Puntuneri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-puntuneri]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]. (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]
 CC: Diamond, Michael [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Conson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
 [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C
 [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
 [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
 [(b) (6) Mason, Stephen [Stephen. (b) (6) (b) (6) ;
 Connelly, Sarah [(b) (6) (b) (6) Gonzalez, Nina [(b) (6)
 Reynolds, Lindsey [(b) (6)

Location: <https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUj8PMVZLUjhCY2RqROQ2QT09>

Start: 11/5/2020 3:00:00 PM

End: 11/5/2020 4:00:00 PM

Show Time As: Tentative

Recurrence: (none)
 every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: (b) (6) Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) ; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
 (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];
 Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];
 Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)
Optional Attendees: Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];
 Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E];
 Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam,
 Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel,
 Jonathan, Prabhavathi Fernandes; Rose Li; Dana Carluccio, Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha
 (NIH/NCATS) [E]; Gonzalez, Nina, Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D;
 Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood;
 Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen;
 (b) (6) Connelly, Sarah; (b) (6) Reynolds, Lindsey

While not unanimous, more people were able to make the 5th at 10am. We will go over the discussion at the Executive committee meeting, future strategic topics and then our normal reviews.

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUj8PMVZLUjhCY2RqROQ2QT09>

(b) (6)

Meeting ID: (b) (6)

Passcode: (b) (6)

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Dial by your location

(b) (6)

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US (Chicago)

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US (San Jose)

US (San Jose)

US (Tacoma)

US (Houston)

Meeting ID: (b) (6) 854

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

Sent: 8/28/2020 1:14:33 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference
Attachments: 8.26 ACTIV Leadership Team Meeting 20200825 vFinal.pptx

From: George, Jill (NIH/OD) [E] <(b) (6)>
Sent: Friday, August 28, 2020 9:12 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Darn. These are all PDFs. Any PPTX files?

From: Parker, Ashley (NIH/OD) [E] <(b) (6)> v>
Sent: Friday, August 28, 2020 8:49 AM
To: George, Jill (NIH/OD) [E] <(b) (6)>
Subject: FW: Materials for August 26 ACTIV Partnership Leadership Team Teleconference
Importance: High

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, August 25, 2020 9:47 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
(b) (6) >; Carter, Kara (b) (6) Cavaleri, Marco
Cihlar, Tomas (b) (6) >; Collins, Francis (NIH/OD) [E]
(b) (6) Corey, Larry (b) (6) >; Culp, Michelle (NIH/OD) [E] <(b) (6)>
Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael <(b) (6)> Erbeling,
Emily (NIH/NIAID) [E] (b) (6) >; Erck, Stan (b) (6) Fauci, Anthony (NIH/NIAID) [E]
(b) (6) >; Freire, Maria (FNIH) [T] (b) (6) ; Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Hudson, Thomas
(b) (6) >; James, Stephanie (FNIH) [T] (b) (6) ; Johnson, Robert (OS/ASPR/BARDA)
(b) (6) >; Kramer, Lynn (b) (6) ; Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Lepore, John <(b) (6)> Marks, Peter (FDA/CBER) (b) (6) Marston, Hilary
(b) (6) >; Mascola, John (NIH/VRC) [E] (b) (6) Meeker, David
<(b) (6)> Menetski, Joseph (FNIH) [T] (b) (6) Messonnier, Nancy
(CDC/DDID/NCIRD/OD) (>V>; Pandya, Hitesh (b) (6) >; Pangalos, Mene
(b) (6) >; Pao, William (b) (6) . Parker, Ashley (NIH/OD) [E]
(b) (6) Paul, Steve (b) (6) >; Perlmutter, Roger (b) (6) (b) (6)
Plenge, Robert <(b) (6)> >; Plump, Andy <(b) (6)> >; Rachel Ramoni
<(b) (6)> Rasi, Guido (b) (6) ; Reed, John <(b) (6)> Reese, David
(b) (6) ; Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Skovronsky,
Daniel (. Stein, Peter (FDA/CDER) (Stoffels, Paul
(b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) ; Talley, Michael
(b) (6) >; Tsai, John <(b) (6)> (Vessey, Rupert <(b) (6)> >; Virgin, Skip
(b) (6) >; Wholley, David (FNIH) [T] (b) (6) : Woodcock, Janet (FDA/CDER)
(b) (6) >; Young, John) (b) (6) ; Colvis, Christine (NIH/NCATS) [E]
(b) (6) Desrosiers, Betsy <(b) (6)> Eric Hughes
(b) (6) >; Jansen, Kathrin (b) (6) . Kurilla, Michael (NIH/NCATS) [E]

(b) (6) , Lowy, Douglas (NCI) (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6)
 Young, John (b) (6)
 Cc: Adam, Stacey (FNIH) [T] (b) (6) >; Alvarez, Rosa (b) (6) >; Anderson, Margaret
 (b) (6) Chen, Helen < (b) (6) Elsaid, Olivia (b) (6)
 Gonzalez, Nina (b) (6) >; Hawk, Harrison (b) (6) >; Menetski, Joseph (FNIH) [T]
 <j (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) ; Stratton, Benjamin (b) (6) >;
 btolman (b) (6) , Tountas, Karen (FNIH) [T] (b) (6) >; Wachtel, Jonathan
 (b) (6) Wholley, David (FNIH) [T] (b) (6) Anderson, James (NIH/OD) [E]
 >; Austin, Christopher (NIH/NCATS) [E] (b) (6) ; Burklow, John (NIH/OD) [E]
 (b) (6) ; Castillejos, Carlos < (b) (6) : Culp, Michelle (NIH/OD) [E]
 (b) (6) FNIH Central Account (b) (6) >; Freire, Maria (FNIH) [T]
 (b) (6) ; Gadbois, Ellen (NIH/OD) [(b) (6) >; Hallett, Adrienne (NIH/OD) [E]
 < (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Myles, Renate (NIH/OD) [E]
 (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E]
 < (b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6) >; Burklow, John (NIH/OD) [E]
 (b) (6) Gorman, Greta (FNIH) [T] (b) (6) . Hallett, Adrienne (NIH/OD) [E]
 (b) (6) ; Meltzer, Abbey (FNIH) [T] (b) (6) Myles, Renate (NIH/OD) [E]
 < (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6) . Lucas Smalldon
 (b) (6) ; Villafana, Tonya (b) (6) ; Brian Rosen
 (b) (6)

Subject: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Importance: High

Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/15/2020 6:08:29 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups
Attachments: Master list for ACTIV 041520.xlsx

Francis -- the following emails were missing from the list that went out, please see 8 emails listed below

Cheryl -- attached is a revised master list (114 contacts) with names and emails which includes everyone.

Disbrow, Gary (OS/ASPR/BARDA) < (b) (6)>
Kim, Elizabeth < (b) (6)>
Marston, Hilary (NIH/NIAID) [E] < (b) (6)>
Paul, Steve < (b) (6)>
Payne, David < (b) (6)>
Plump, Andy < (b) (6)> ;
Santos, Nancy < (b) (6)>
Shen, Yuan Li (FDA/CDER) < (b) (6)> ;

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] < (b) (6)>
Sent: Wednesday, April 15, 2020 11:39 AM
To: Melencio, Cheryl (FNIH) [T] < (b) (6)> Parker, Ashley (NIH/OD) [E] < (b) (6)>
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

I already sent the other list, given the time sensitivity. What has been added here that wasn't in the other one?

From: Melencio, Cheryl (FNIH) [T] < (b) (6)> < (b) (6)>
Sent: Wednesday, April 15, 2020 11:19 AM
To: Parker, Ashley (NIH/OD) [E] < (b) (6)> Collins, Francis (NIH/OD) [E] < (b) (6)>
Subject: List -- just copy and paste in bcc. lists of April 3 plus working groups

Austin, Christopher (NIH/NCATS) [E] < (b) (6)> Bright, Rick < (b) (6)> Collins, Francis (NIH/OD) [E] < (b) (6)> >; Corey, Larry < (b) (6)> >; Disbrow, Gary (OS/ASPR/BARDA) < (b) (6)> >; Dolsten, Mikael < (b) (6)> >; Erbeling, Emily (NIH/NIAID) [E] < (b) (6)> >; Fauci, Anthony (NIH/NIAID) [E] < (b) (6)> >; Frankowski, David < (b) (6)> >; James, Stephanie (FNIH) [T] < (b) (6)> >; Klock, Kevin (FNIH) [T] < (b) (6)> Lane, Cliff (NIH/NIAID) [E] < (b) (6)> >; Marks, Peter (FDA/CBER) < (b) (6)> >; Marston, Hilary (NIH/NIAID) [E] < (b) (6)> >; Mascola, John < (b) (6)> >; Meeker, David < (b) (6)> Menetski, Joseph (FNIH) [T] < (b) (6)> >; Pangalos, Mene < (b) (6)> Pao, William < (b) (6)> >; Paul, Steve < (b) (6)> >; Perlmutter, Roger < (b) (6)> Plump, Andy < (b) (6)> >; Rasi, Guido < (b) (6)> Reed, John < (b) (6)> >; Rouse, < (b) (6)>

Doris (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) Skovronsky, Daniel
 (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) >; Stoffels, Paul
 < (b) (6) ; Tabak, Lawrence (NIH/OD) [E] < (b) (6) ; Tsai, John
 (b) (6) >; Vessey, Rupert (b) (6) ; Virgin, Skip (b) (6) ; Wholley, David
 (FNIH) [T] (b) (6) >; Woodcock, Janet (FDA/CDER) (Young, John
 < (b) (6) Adam, Stacey (FNIH) [T] (b) (6) ; Bascles, Lionel
 (b) (6) >; Cohen, Myron < (b) (6) Corey, Larry (b) (6) >;
 Desrosiers, Betsy (b) (6) Dickens, Jim (NIH/NCATS) [C] < (b) (6) >;
 Doroshov, James (NIH/NCI) [E] (b) (6) >; Goff, David (NIH/NHLBI) [E] < (b) (6) Heaton,
 Penny < (b) (6) King, James (b) (6) >; Kurilla, Mike (b) (6) ; Nayak,
 Seema (NIH/NIAID) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) Payton, Manzine
 (b) (6) Resnansky, Laura (b) (6) ; Srinivasan, Badhri
 (b) (6) Stein, Peter (FDA/CDER) (b) (6) ; Tountas, Karen (FNIH) [T]
 (Vincent, Mike < (b) (6) >; Wachtel, Jonathan (b) (6)
 Woodcock, Janet (FDA/CDER) < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Bozzette,
 Sam (NIH/NCATS) [E] (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) (b) (6) >;
 Butters, Joan (b) (6) De Claro, R. Angelo (FDA/CDER) < (b) (6)
 Draghila-Akli, Ruxandra < (b) (6) Elsner, Mark < (b) (6) Gottesdiener, Keith
 (b) (6) ; Hughes, Eric (b) (6) ; Judy Currier
 < (b) (6) Kim, Elizabeth (b) (6) >; LaVange, Lisa (b) (6) Levy, Elliot
 (b) (6) >; Mellors, John < (b) (6) Menon, Sandeep < (b) (6) Parker,
 Ashley (NIH/OD) [E] (b) (6) ; Patel, Naimish (b) (6) Peppercorn, Amanda
 (b) (6) Poole, Mike < (b) (6) ; Proschan, Michael
 (b) (6) Read, Sarah < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Shen,
 Yuan Li (FDA/CDER) (b) (6) Stein, Peter (FDA/CDER) < (b) (6) >; Adams, Peter
 (OS/ASPR/BARDA) (b) (6) ; Alvarez, Rosa (b) (6) >; Anderson, Annaliesa
 (b) (6) Baric, Ralph < (b) (6) Carter, Kara (b) (6)
 Colvis, Christine (b) (6) Deming, Damon (FDA/CDER) < (b) (6) Diamond,
 Michael (b) (6) ; Duncan, Ken (b) (6) ; Fernandes, Prabhavathi
 (b) (6) ; Gatto, Greg (b) (6) Grobler, Jay (b) (6) Hewitt, Judith
 (b) (6) ; Jonson, Samantha (NIH/NCATS) [E] (b) (6) >; Lutz, Cat (b) (6)
 Menetski, Joseph (FNIH) [T] < (b) (6) Nestle, Frank (b) (6) >; Ottinger, Liz
 (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6) Payne, David
 < (b) (6) Rappaport, Jay (b) (6) Stegmeier, Frank <f> (b) (6)
 Young, John < (b) (6) Annunziato, Paula (b) (6) Arvin, Ann
 (b) (6) Buchbinder, Susan (b) (6) ; Corey, Larry (b) (6) >;
 Davis, Mark < (b) (6) Ermini, Emilio < (b) (6) Hanon, Emmanuel
 < (b) (6) Haynes, Barton < (b) (6) Hotez, Peter < (b) (6) Jansen,
 Kathryn (b) (6) Lanzavecchia, Antonio (b) (6) Lowy, Douglas (NIH/NCI) [E]
 < (b) (6) Marks, Peter (FDA/CDER) (b) (6) >; Mascola, John (NIH/VRC) [E]
 < (b) (6) >; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (Offit, Paul
 (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6) Santos, Nancy (b) (6) >;
 Schuitemaker, Hanneke < (b) (6) Tartaglia, Jim < (b) (6) Tolman, Brett
 (b) (6) (b) (6) (b) (6)

Cheryl Melencio

Administrative Manager, Research Partnerships
 Foundation for the National Institutes of Health
 (b) (6)

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/1/2020 4:05:00 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: Confirm Attendance: July 1 ACTIV Leadership Call #5
Flag: Follow up

From: Erbeling, Emily (NIH/NIAID) [E] <(b) (6)>
Sent: Wednesday, July 1, 2020 9:04 AM
To: Wholley, David (FNIH) [T] <(b) (6)>
Cc: Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: RE: Confirm Attendance: July 1 ACTIV Leadership Call #5

David,
I can't join the ACTIV call today. I have an Operation Warp Speed call with Moncef Slaoui at the same time.
Sorry.
Emily

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Wednesday, July 1, 2020 7:59 AM
To: Erbeling, Emily (NIH/NIAID) [E] <(b) (6)>
Cc: Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: FW: Confirm Attendance: July 1 ACTIV Leadership Call #5

Hi Emily, Will you be on today's call, and can you please confirm back to Cheryl and me? Thanks, David Wholley

From: Melencio, Cheryl (FNIH) [T] <(b) (6)>
Sent: Monday, June 29, 2020 1:18 PM
To: Cavaleri, Marco <(b) (6)> Cihlar, Tomas <(b) (6)> Disbrow, Gary <(b) (6)>
(OS/ASPR/BARDA) <(b) (6)> Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> Lee, William <(b) (6)> Lepore, John <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)>
>; Meeker, David <(b) (6)> ; Messonnier, Nancy (CDC/DD D/NCIRD/OD) <(b) (6)>
>; Plenge, Robert <(b) (6)> Reed, John <(b) (6)>
>; Skovronsky, Daniel <(b) (6)> ; Stein, Peter (FDA/CDER) <(b) (6)>
<(b) (6)> Talley, Michael <(b) (6)> ; Vessey, Rupert <(b) (6)> >; Woodcock, Janet (FDA/CDER) <(b) (6)> >; Jansen, Kathrin <(b) (6)>
Cc: Giorgi, Sara <(b) (6)> Dimishkov, Roxanne (NIH/NHLBI) [C] <(b) (6)>
MacDougall, Cheryl <(b) (6)> Thomas, Ashley (FDA/CDER) <(b) (6)>
Subject: Confirm Attendance: July 1 ACTIV Leadership Call #5

Good afternoon,

Please confirm your attendance for the ACTIV Leadership Call on Wednesday, July 1 – 1-2:30 p.m. Eastern time.

Thank you for your assistance.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Connelly, Sarah [(b) (6)]
Sent: 11/4/2020 11:25:22 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];
 (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; m;
 (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
 (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
 (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
 (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6))
CC: Diamond, Michael [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi
 Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio
 (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses];
 Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=Sbbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
 [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C
 [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; Stratton, Benjamin
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188];
 Gadbois, El en (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
 Mason, Stephen [(b) (6) (b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Dear Preclinical Working Group Members,

Please see below for the agenda for tomorrow's meeting at 10:00 AM ET. If you have any questions or items to add, please let us know.

Agenda Topic	Duration	Facilitator
11/4 ACTIV Executive Committee meeting - Updates	15 mins	John Young Christine Colins Joe Menetski
HSPD-21 (National Strategy for Public Health and Medical Preparedness) - Updates	15 mins	Prabha Fernandes
Discuss Sub Group updates		John Young
o Preclinical prioritization		Nancy Haigwood
o in vivo strategy		Clint Florence
NHP field guide	20 mins	Carl Lutz
o Small animal model field guide		Eris Kanevsky
o Data portal implementation		Sam Jonson
Align on action items and next steps	10 mins	Joe Menetski Sarah Connolly

Looking forward to talking to everyone tomorrow!

All the best,
 Sarah

Sarah Connolly, PhD
 Deloitte Consulting, LLP
 Tel/Direct: (b) (6)
 www.deloitte.com

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] <(b) (6)>

Sent: Friday, October 2, 2020 2:19 PM

To: Menetski, Joseph (FNIH) [T]; (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine
(NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER), (b) (6)

(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas
Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc
(NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Cc: Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];
Desrosiers, Betsy; Eric Hughes, Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah
(NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH)
[T]; A varez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana
Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C];
Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski, Baric, Toni C, Lowy, Douglas (NIH/NCI) [E];
Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James
(NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6) Connelly, Sarah;
(b) (6)

Subject: ACTIV Preclinical full working group

When: Thursday, November 5, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom> (b) (6)

While not unanimous, more people were able to make the 5th at 10am. We will go over the discussion at the Executive committee meeting, future strategic topics and then our normal reviews.

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

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v.E.1

Sent: 5/15/2020 1:44:15 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: Time sensitive: Making your ACTIV Participation Public
Attachments: Leadership National Institutes of Health (NIH).pdf

Hi Lauren,

One thing that would be helpful – can we cross check the updated list Renate shared with the attached spreadsheet of emails

From: Myles, Renate (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 15, 2020 9:21 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>; Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Allen-Gifford, Patricia (NIH/OD) [E] <(b) (6)>; Wooldridge, Shannon (NIH/OD) [E] <(b) (6)>; Pollock, Rachel (NIH/OD) [E] <(b) (6)>
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Ashley:

Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 15, 2020 9:11 AM
To: Myles, Renate (NIH/OD) [E] <(b) (6)>; Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Allen-Gifford, Patricia (NIH/OD) [E] <(b) (6)>; Wooldridge, Shannon (NIH/OD) [E] <(b) (6)>; Pollock, Rachel (NIH/OD) [E] <(b) (6)>
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Renate,

I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking.

We can send follow up emails to everyone except for those three – they will need to be contacted.

Moving forward, it may be best for you to receive updates from the communications team – FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

(b) (6)

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

(b) (6)

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

(b) (6)

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.

(b) (6)

Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory

(b) (6) 5)

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

(b) (6) 5) (6)

Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

(b) (6)

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

(b) (6)

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

(b) (6)

Frank Stegmeier, Ph.D.

Chief Scientific Officer
KSQ Therapeutics

(b) (6) m

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

(b) (6)

Judith Currier, M.D.

Professor of Medicine

University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)

(b) (6)

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

(b) (6)

Elliot Levy, M.D.

Senior Vice President, Global Development
Amgen

(b) (6)

Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi

(b) (6)

Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs
Eli Lilly and Company

(b) (6)

Peter Stein, M.D.

Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

(b) (6)

Beth Bell, M.D., MPH

Clinical Professor, Global Health
University of Washington

(b) (6)

Emilio Emini, Ph.D.

Director, TB & H V Program
Bill & Melinda Gates Foundation

(b) (6)

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

(b) (6)

Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

(b) (6)

Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

(b) (6)

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

(b) (6)

From: Myles, Renate (NIH/OD) [E] (b) (6)

Sent: Friday, May 15, 2020 7:53 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Allen-Gifford, Patricia (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Wooldridge, Shannon (NIH/OD) [E] <(b) (6)> Pollock, Rachel (NIH/OD)
[E] (b) (6)

Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Francis:

Below is the list of 23 people who have not yet responded to your email. I cross referenced these names with the email list that Ashley sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.

(b) (6)

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.

Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

Frank Stegmeler, Ph.D.

Chief Scientific Officer
KSQ Therapeutics

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

Judith Currier, M.D.

Professor of Medicine
University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)

(b) (6)

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

(b) (6)

Elliot Levy, M.D.

Senior Vice President, Global Development
Amgen

(b)

(6)

Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi

(b) (6)

m

Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs
Eli Lilly and Company

(b) (6)

Peter Stein, M.D.

Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
(b) (6)

Beth Bell, M.D., MPH

Clinical Professor, Global Health
University of Washington

Emilio Emini, Ph.D.

Director, TB & H.V Program
Bill & Melinda Gates Foundation
(b) (6)

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer
(b) (6)

Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland
(b) (6)

Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
(b) (6)

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Myles, Renate (NIH/OD) [E] ; Meltzer, Abbey (FNIH) [T] (b) (6) >; Wholley, David (FNIH) [T] (b) (6)

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Tountas Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]

Sent: 5/5/2020 1:58:10 AM

To: Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Bascles, Lionel [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6) Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshov]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King]; Kurlla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6) Srinivasan, Badhri [(b) (6) Wachtel, Jonathan [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]

CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot [(b) (6) Anderson, Margaret [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6) Hamilton, Nancy [(b) (6) Minnich, Beth [bmminnich@fredhutch.org]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER)

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Stratton, Benjamin
[(b) (6) Tolman, Brett [(b) (6) Garner, Carlos [(b) (6)
Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich
[(b) (6)

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Attachments: Clinical Trial Capacity Working Group Meeting Agenda 05052020.pdf; Network survey responses 04 May 2020.pdf;
Site survey responses 04May2020.pdf; DRAFT CRO survey.docx

Location: <https://zoom.us/j/> (b) (6)

Start: 5/5/2020 1:00:00 PM

End: 5/5/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Stein, Peter (FDA/CDER); Vincent, Mike; Woodcock, Janet (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Bascles, Lionel;

Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srivivasan, Badhri; Wachtel, Jonathan; Qashu, Felicia

Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Anderson, Margaret; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John Adam; Stacey (FNIH) [T];

Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6)

Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Garner, Carlos; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues,

Attached is the meeting agenda along with current survey results (40 networks and 463 sites to-date'). In addition, attached are draft questions to consider for the CRO survey that will be discussed, but please note that some questions are carried over from the network survey for consideration (editing or deleting). Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

Join Zoom Meeting

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(b) (6)

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(b) (6)

From: Koroshetz, Walter (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8338DD7CDCD432E986961F1548C5EC6-KOROSHETZW]
Sent: 5/14/2020 6:07:04 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; [(b) (6)]; [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

My mistake on call today. Now see that tocilizumab binds to both the membrane and the soluble IL6 Receptor So gets at both modes of signaling.
 walter

From: Adam, StaMycey (FNIH) [T] < (b) (6) >
Sent: Thursday, April 30, 2020 7:11 PM
To: Eric Hughes < (b) (6) >; Read, Sarah (NIH/NIAID) [E] < (b) (6) >; Ruxandra Draghia-Akli < (b) (6) >; Mellors, John W < (b) (6) >; Naimish Patel < (b) (6) >; Colvis, Christine (NIH/NCATS) [E] < (b) (6) >; Young, John < (b) (6) >; Stein, Peter (FDA/CDER) < (b) (6) >; Poole, Mike < (b) (6) >; Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) >; Vincent, Michael < (b) (6) >; Keith Gottesdiener < (b) (6) >; Elliott Levy < (b) (6) >; Wung, Peter /US < (b) (6) >; Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) >; Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) >; Carlos O Garner < (b) (6) >
Cc: Elizabeth Kim < (b) (6) >; Menetski, Joseph (FNIH) [T] < (b) (6) >; Alvarez, Rosa Maria < (b) (6) >; Salathin, Carla < (b) (6) >; GM < (b) (6) >; J < (b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) >; Wholley, David (FNIH) [T] < (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6) >; Lucas Smalldon < (b) (6) >; Walker, Paula (NIH/NINDS) [E] < (b) (6) >; Ward, Jackie (NIH/NINDS) [E] < (b) (6) >
Subject: RE: Follow up Materials to ACTIV Therapeutics Clinical Agent Prioritization Subgroup Meeting #5 Including New Score Sheet (Agents Added)

Hi All,

This is the second email. It has the anticoag information.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Adam, Stacey (FNIH) [T]
Sent: Thursday, April 30, 2020 7:05 PM
Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)
Importance: High

Dear TX-Clinical Agent Prioritization Subgroup,
I appreciate the candid and productive meeting that we had today. All your feedback is very helpful to refine our process for the next time.

For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some if this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

1. The summary spreadsheets for the agents in the host targeted category that have been added from the R&D Consortium group + 1 for Firazyr as it was requested. (one note, the group shared with us Firazyr is likely be tested in a few other trials, so that may need to be considered)
2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.
3. An article relevant to immune modulator use in COVID-19.
4. Articles for the Antiviral group on some preclinical testing work.
5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but EIDD-2801.
 - a. *"All of these compounds except EIDD-2801 are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here <https://reframedb.org/assays/A00440>. You can create an account for free and search the data."*

Please find attached the updated spreadsheet with all the new relevant compounds added for the groups to vote on. These new compounds for your groups are highlighted in green.

Finally, please find below the captured action items and key takeaways from the meeting.

Action Items

Action Items
Information

POC

1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy / Stacey Adam
2	Send updated score sheets Agent Prioritization Review Committee members	Stacey Adam
3	(immunomodulators) score additional agents that have been added from the R&D Consortium list Getting standardized, reliable data on the agents	AP Sub Group Members Stacey Adam /
4	<ul style="list-style-type: none"> Trans-NIH information, intramural and extramural Mike Poole, Gates Foundation 	Ruxandra Draghia-Akli
5	Ask Preclinical Working Group (R&D members) for relevant data on agents if available	Joe Menetski
6	Get data on antivirals from NIAID and NCATS	Sarah Read/Christine Colvis

Key Takeaways

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More research needed on drugs to understand whether these are worth putting into clinical trials. Need for more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) Mobile: (b) (6)
fnih.org
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[(b) (6) Gottesdiener, Keith [(b) (6) Judy Currier
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 [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364];
 Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];
 Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike
 [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham];
 Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER)
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Kurilla, Michael (NIH/NCATS)
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Melencio, Cheryl (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Gonzalez, Nina
 [(b) (6) Stratton, Benjamin [(b) (6) Qashu, Felicia (NIH/OD) [E]
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 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Hoots, W. Keith
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
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 (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
 Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
 [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6)
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose
 Li Central Account [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative
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 [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; (b) (6) Mollica, Linda /US
 [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B.
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen Q.
 [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)
CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]

Subject: Canceled: ACTIV Therapeutics-Clinical Working Group Meeting

Start: 8/20/2020 5:00:00 PM

End: 8/20/2020 6:00:00 PM

Show Time As: Free

Recurrence: (none)

Required Attendees: Draghia-Ak I, Ruxandra; Butterson, Joan; Hughes, Eric; Bozzette, Sam (NIH/NCATS) [E]; De Claro, R. Angelo
(FDA/CDER); Eisner, Mark; Gottesdiener, Keith; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John;
Menon, Sandeep Parker, Ashley (NIH/OD) [E]; Patel, Namish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael,
Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH)
[T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs,
Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];
Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6)
Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner;
Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - O449 - MITLL;
(b) (6) Sizemore, Christine (NIH/FIC) [E]

Dear ACTIV TX-Clinical WG,

we were unable to find a suitable time to reschedule this week's meeting for to accommodate our
presenters. Therefore, we will just cancel for this week. Please enjoy the neutralizing Ab Summit on
Thursday!

Thanks,
Stacey

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Sent: 5/20/2020 6:16:30 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6)]; LaVange, Lisa M [(b) (6)]; Sandeep Menon [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6)]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; Eron, Joe [(b) (6)]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [(b) (6)]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]
CC: Demarcus [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Elizabeth Kim [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6)]; Eron, Joseph J Jr [(b) (6)]; Smith, David [(b) (6)]; Paul Klekotka [(b) (6)]; Ajay Nirula [(b) (6)]; Elsaid, Olivia [(b) (6)]; Robert Jan Benschop [(b) (6)]; Lei Shen [(b) (6)]
Subject: RE: Follow-up from ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting

Dear ACTIV TX-Clinical mAb Outpatient WT,

It looks like we can get about ¾ of the group together tonight. Would the group still like to meet from 6-7pm ET.

In the thought that I think we will want to, I am going to send a calendar hold with a zoom link just in case.

Thanks,
STacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) , Mobile: (b) (6)

From: Adam, Stacey (FNIH) [T]
Sent: Tuesday, May 19, 2020 11:05 PM
Subject: Follow-up from ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting

APAR0000005359-2516527

Dear ACTIV TX-Clinical mAb Outpatient WT,

Thank you all for a very productive meeting today. I think we covered a lot of group, and while I know we still have a lot more to cover, we made some progress!

I am attaching the notes that our Deloitte colleague Olivia was kind enough to capture for us, and I have attached both Lisa and Karen's and Michael's slide set for the group's reference. Please let me know if you have questions on any of these.

In addition, I am attaching a protocol synopsis that the ACTG team was kind enough to draft up to space me splicing together slides tomorrow for the presentation to the ACTIV mAb Master Protocol Steering Committee who will meet to review tomorrow.

For this group, I would like to get our next meeting on the books. **Time may be tight tomorrow due to a number of other meetings. Does the group want to shoot for an evening call, starting around 5:30 or 6pm ET?** Please let me know what might work for you and I will see if we can get quorum.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) Mobile: (b) (6)
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/16/2020 12:03:08 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Wolinetz, Carne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: RE: PLEASE READ Draft Email to Collect Communication Contact Information

Good morning Renate,

Our rep at Takeda, Andy Plump is included on the master list. I am confirming with Francis that he used our master list for his email that went out last night – **I should be able to confirm this for you this morning.**

I hope you are staying safe and healthy; maybe even getting some rest in between the constant COVID activities.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] <(b) (6)>
Sent: Thursday, April 16, 2020 7:14 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>
Subject: FW: PLEASE READ: Draft Email to Collect Communication Contact Information
Importance: High

Hi Ashley:

I'm not sure if Francis added a Takeda contact to his email. I could not find one on the master contact list. I have not heard from their organizations yet. Would you let me know if you provided that to him last night or if they are missing from this email? Need to send it to this group this morning.

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]
Sent: Wednesday, April 15, 2020 9:11 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Wood, Gretchen (NIH/OD) [E] <(b) (6)>; McManus, Ayanna (NIH/OD) [E] <(b) (6)>; Burklow, John (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: PLEASE READ: Draft Email to Collect Communication Contact Information
Importance: High

Hi Francis:

We need to collect the communication contacts from the partner organizations so we can share the release with them for review. Below is 1) a draft email for you to send to the company participants, 2) the contacts for the companies we list in the release except for Takeda (I could not find a Takeda contact on the master list; hoping Ashley can provide); 3) those who should be copied (feel free to add others).

Dear ACTIV colleagues:

As I mentioned earlier today, we would like to announce the plans for a public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at [(b) (6)] and Abbey Meltzer (b) (6)) this evening, if possible.

BCC:

(b) (6)

CC:

(b) (6)

Thanks,
Renate

From: Santos, Michael (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]

Sent: 7/31/2020 2:56:17 AM

To: (b) (6) (b) (6) (b) (6) Cohen, Myron
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron.cohen];
 (b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingel]; (b) (6)
 (b) (6) (b) (6) Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda];
 (b) (6) Hamilton, Hollis (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Hollis.Hamil];
 (b) (6) (b) (6) Ledgerwood, Julie (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood];
 (b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Marks, Peter (FDA/CBER)
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643acc6347728dbaeb-marovichma]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Nelson Michael
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha];
 (b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Offit, Paul
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56f6be4598a57b423d484dcf9f-offit.email]; Merlin Robb
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6442891c7f7b404486500d6ed251a686-MerlinRobb];
 (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7248415bb86087d08b628e6f-melencioc]; Laurent Humeau
 [(b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Parker, Ashley (NIH/OD) [E]
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 (b) (6) Hotez, Peter Jay [(b) (6) (b) (6) Tal Zaks
 [(b) (6) (b) (6) Greg Glenn [(b) (6)
 (b) (6) Gebo, Kelly (NIH/OD) [G] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=009cf99ae63f4f71b5b1204a73ded609-geboka]; Jacqueline Miller
 [(b) (6) François P Roman [(b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) (b) (6) Johnson, Maureen (NIH/NCI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Soriano Osejo, Douglas
 [(b) (6) Stratton, Benjamin [(b) (6) Sitar, Sandra (NIH/VRC) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=79e781b1f84a4f878583062a6ae87017-sitars]; Tong, Tina (NIH/N.AID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=79a14013c7204460809b8c4213282808-tongtl]; Kuril a, Michael (NIH/NCATS)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Tountas, Karen (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A.
 [(b) (6) Isabel Ramsey [(b) (6) Sridhar, Saranya /US
 [(b) (6) Brian Rosen [(b) (6) Cheryl Keech [(b) (6) Sadoff,
 Jerald [JRDUS] [(b) (6) m]; Michael, Nelson [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=05b9ca6b24634974b7aeb3fcaead1623-nmichael.hi]; Kayvon Modjarrad
 [(b) (6)

Subject: Notes from the Vaccines Clinical Trials Sub-Group meeting

Attachments: 2020-07-23 Vaccines Clinical Trials Sub-Group meeting Notes.docx; Statistical Considerations (ACTIV July 23)
 FINAL.pptx

Dear Vaccines Clinical Trials Sub-Group,

With apologies for the delay, attached are the notes and materials from last week's meeting. Our thanks to Devan Mehrotra and colleagues for presenting their considerations on trial endpoints with the group.

Also, we are rescheduling the meeting originally planned for this week so that we can find a time for the regulatory representatives in our group to share their perspectives on the implications of the first successful vaccine for other vaccines in development. We're very much looking forward to that discussion.

In addition, going forward we intend to shift the scheduling of this group's meetings to every other week, which we hope will balance addressing key topics in a timely manner with being good stewards of everyone's time. Please reach out any time with recommended topics or questions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, July 22, 2020 5:25 PM
Subject: Agenda for tomorrow's Vaccines Clinical Trials Sub-Group meeting and notes from last meeting

Dear Vaccines Clinical Trials Sub-Group,

We're looking forward to our meeting tomorrow (Thursday) at 2pm ET (11am PT / 8pm CEST). We're delighted to welcome Devan Mehrotra from Merck to present on considerations for the efficacy endpoint of trials, and in particular the potential value of a burden of disease endpoint. These are concepts developed in collaboration with Jon Hartzel, Dean Follmann, and Peter Gilbert, who will also be at the meeting. Their slides are attached.

We are also sharing notes and materials from our last meeting, with particular thanks to Beth Bell and Paul Ostrowski for their presentations. A couple of related notes following up from the ACIP presentation that Beth gave:

- The first meeting of the [National Academies of Medicines project on "A Framework for Equitable Allocation of Vaccine for the Novel Coronavirus"](#) is Friday, including an open session (registration available at the link).
- The next [ACIP meeting](#) is 29 July (agenda available at the link)

Please don't hesitate to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Thursday, July 16, 2020 12:36 PM
Subject: Agenda for tomorrow's Vaccines Clinical Trials Sub-Group meeting

Dear Vaccines Clinical Trials Sub-Group members,

We're looking forward to our meeting tomorrow (Friday) at 12:30pm ET (9:30am PT / 6:30pm CEST).

At our last meeting we discussed the implications of the first vaccine success for ongoing and new efficacy trials. Part of that process will be access to the first successful vaccine after regulatory authorization/approval, and access will depend on the regulatory approval and normative guidance (to prioritize populations) and vaccine supply and delivery.

We're delighted to have those two topics on the agenda for tomorrow's meeting:

- ACIP guidance process: Beth Bell, who is the chair of the COVID-19 ACIP Work Group
- Vaccine supply and delivery: Paul Ostrowski of Operation Warp Speed, who leads the OWS supply, production and distribution directorate

For scheduling reasons we'll have the discussion of vaccine supply and delivery first.

Also of note, the June 24 ACIP meeting sessions, which include a session on '[COVID 19 vaccine prioritization considerations](https://www.cdc.gov/vaccines/acip/meetings/live-mtg-2020-6.html)' are now available online: <https://www.cdc.gov/vaccines/acip/meetings/live-mtg-2020-6.html>. Thanks to Jackie for mentioning this last week and Beth for pointing us to the webpage.

As always, please reach out with any questions or input.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
(b) (6) fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/30/2020 12:30:31 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Collis]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fda]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6) Pamela Tenaerts, M.D. [(b) (6) Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #13
Location: <https://fnih.zoom.us/> (b) (6)

Start: 5/6/2020 6:00:00 PM
End: 5/6/2020 7:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne

(FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER). Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E], Vincent, Michael; Wung, Peter /US; Karen Lynn Price, Pamela Tenaerts, M.D.
Optional Attendees: Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

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US (Houston)

US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom> (b) (6)

From: Menon, Sandeep M [(b) (6)]
Sent: 5/21/2020 1:00:58 PM
To: Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; LaVange, Lisa M [(b) (6)]; Eron, Joseph J Jr (b) (6); Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6)]; Wohl, David A [(b) (6)]; Fischer, William A. II (b) (6) [william_fischer@med.unc.edu]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; LH (b) (6); Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [(b) (6)]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: DeMarcus, Forrest [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Elizabeth Kim [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6)]; Smith, David [(b) (6)]; Paul Klekotka [(b) (6)]; Ajay Nirula [(b) (6)]; Elsaid, Olivia [(b) (6)]; Robert Jan Benschoep [(b) (6)]; Lei Shen [(b) (6)]
Subject: Re: [EXTERNAL] RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Agree Mike and Lisa. Not worried about the stats rules, the basic question is what we discussed yesterday. Do we have enough confidence in the assay and the quantitative cut offs and whether it correlates to the clinical endpoint early enough. I am assuming the decision for futility or efficacy stopping will be based on clinical endpoint (and not just the viral load). Based on the discussion yesterday, I heard that we were not sure that viral load correlates with the clinical endpoint.

From: "Proschan, Michael (NIH/NIAID) [E]" < (b) (6) >
Date: Thursday, May 21, 2020 at 8:52 AM
To: "LaVange, Lisa M" < (b) (6) > "Eron, Joseph J Jr" < (b) (6) > "Adam, Stacey (FNIH) [T]" < (b) (6) > Judy Currier < (b) (6) > Eric Hughes < (b) (6) > Sandeep Menon < (b) (6) > "Read, Sarah (NIH/NIAID) [E]" < (b) (6) > "Rubin, Daniel B." < (b) (6) >

(FDA/CDER)" < (b) (6) "Farley, John (FDA/CDER)" < (b) (6) Karen Price
 < (b) (6) " (b) (6) < (b) (6) (b) (6)
 " (b) (6) < (b) (6) (b) (6) " (b) (6)
 < (b) (6) " (b) (6) < (b) (6) "Wohl, David A"
 < (b) (6) "Fischer, William A. II" < (b) (6) >, "Javan, Arzhang
 (NIH/NIAID) [E]" < (b) (6) "Roa, Jhoanna" < (b) (6) " (b) (6) <LHosey@s-
 3.com>, "Kim, Peter (NIH/NIAID) [E]" < (b) (6) Jonathan Li < (b) (6) "Marks,
 Gilbert (OS/ASPR/BARDA) (CTR)" < (b) (6) "Kozak, Marina (OS/ASPR/BARDA)"
 < (b) (6)
 Cc: "DeMarcus, Forrest" < (b) (6) "Tountas, Karen (FNIH) [T]" < (b) (6)
 "Wachtel, Jonathan" < (b) (6) Elizabeth Kim < (b) (6) "Parker, Ashley
 (NIH/OD) [E]" < (b) (6) Jhoanna Roa < (b) (6) "Smith, David"
 < (b) (6) Paul Klekotka < (b) (6) Ajay Nirula < (b) (6)
 "Elsaid, Olivia" < (b) (6) Robert Jan Benschoop < (b) (6) Lei Shen
 < (b) (6)

Subject: [EXTERNAL] RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think the question is whether we could stop early for efficacy as well as stopping early for futility. That could certainly be incorporated if you think there is a realistic possibility of crossing an efficacy boundary after only 50 people. At the halfway point, the O'Brien-Fleming-like spending function boundary for the z-score is close to 3, so you would have to see a very large z-score to stop that early for efficacy.

Mike.

From: LaVange, Lisa M < (b) (6)
Sent: Thursday, May 21, 2020 7:53 AM
To: Eron, Joseph J Jr < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Judy Currier
 < (b) (6) Eric Hughes < (b) (6) Sandeep Menon
 < (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah
 (NIH/NIAID) [E] < (b) (6) Price, Dionne (FDA/CDER) < (b) (6) Rubin, Daniel B.
 (FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Karen Lynn Price
 < (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) Wohl, David A < (b) (6) Fischer, William A. II
 < (b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) Roa, Jhoanna <jroa@s-
 3.com>; (b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) Jonathan Li < (b) (6)
 Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA)
 < (b) (6)
 Cc: DeMarcus, Forrest < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan
 < (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)
 Jhoanna Roa < (b) (6) Smith, David < (b) (6) Paul Klekotka
 < (b) (6) Ajay Nirula < (b) (6) Elsaid, Olivia < (b) (6) Robert Jan
 Benschoop < (b) (6) Lei Shen < (b) (6)
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

This seems reasonable to me. We can define any basis that we think will be important for dropping dose arms or entire agents, having little to go on at this point in terms of what best predicts hospitalizations
 Lisa

From: Eron, Joseph J Jr
Sent: Wednesday, May 20, 2020 6:23 PM
To: Adam, Stacey (FNIH) [T] < (b) (6) Judy Currier < (b) (6) Eric Hughes
 < (b) (6) LaVange, Lisa M < (b) (6) Sandeep Menon

< (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah
 (NIH/NIAID) [E] < (b) (6) Price, Dionne (FDA/CDER) < (b) (6) Rubin, Daniel B.
 (FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Karen Lynn Price
 (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) Wohl, David A (b) (6) Fischer, William A. II
 (b) (6) (b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) Roa, Jhoanna (b) (6)
 (b) (6) (b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) Jonathan Li < (b) (6)
 Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA)
 < (b) (6)
 Cc: DeMarcus, Forrest < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan
 < (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)
 Jhoanna Roa < (b) (6) Smith, David < (b) (6) Paul Klekotka
 (b) (6)) (6) Ajay Nirula (b) (6)) Elsaid, Olivia < (b) (6) Robert Jan
 Benschop (b) (6) (b) (6) Lei Shen (b) (6))
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Here is my question for the group – especially Michael, John and Lisa

My question is whether there could be an interim “activity” analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible that this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.

- If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm) In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings

Joe Eron MD
 Professor of Medicine
 University of North Carolina at Chapel Hill
 School of Medicine
 (b) (6)

From: Adam, Stacey (FNIH) [T] < (b) (6)

Sent: Wednesday, May 20, 2020 5:42 PM

To: Judy Currier < (b) (6) Eric Hughes < (b) (6) LaVange, Lisa M
 < (b) (6) Sandeep Menon (b) (6) (b) (6) Proschan, Michael (NIH/NIAID) [E]
 < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Price, Dionne (FDA/CDER)
 (b) (6) (b) (6) Rubin, Daniel B. (FDA/CDER) (b) (6) (6) Farley, John (FDA/CDER)
 < (b) (6) Karen Lynn Price <price_karen (b) (6) (b) (6)
 (b) (6) (b) (6) Wohl, David A
 (b) (6)) (6) Fischer, William A. II < (b) (6) >; Eron, Joseph J Jr
 (b) (6) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) Roa, Jhoanna (b) (6) :
 (b) (6) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) Jonathan Li < (b) (6)
 Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA)
 < (b) (6)
 Cc: DeMarcus, Forrest < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan
 < (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)
 Jhoanna Roa < (b) (6) Eron, Joseph J Jr (b) (6) (6) Smith, David
 < (b) (6) Paul Klekotka (b) (6)) (6) Ajay Nirula (b) (6)) (6) Elsaid,

Olivia < (b) (6) Robert Jan Benschop (b) (6) : Lei Shen (b) (6) 5)

Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,
Stacey

Stacey J. Adani, PhD

Director, Cancer

Research Partnerships

Direct: (b) (6) Mobile: (b) (6)

Join Zoom Meeting

<https://fnih.zoom.us/> (b) (6)

Meeting ID: (b) (6)

Password: (b) (6)

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US (New York)

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US (Houston)

US (San Jose)

US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/j> (b) (6)

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/9/2020 9:14:17 PM
To: Chen, Helen Q. [(b) (6)]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Appell, Evan [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]
BCC: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Brodd, Lauren (NIH/OD) [E] [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Helen,

The hover over doesn't work in the PDF document but this will work when you display in presentation mode during the meeting tomorrow (agents in the hover over are those listed on CT.gov for each trial).

OD will work with a developer when this goes live on the ACTIV website to ensure the feature will work.

Thanks,
Ashley

-----Original Message-----

From: Chen, Helen Q. < (b) (6) >
Sent: Wednesday, September 9, 2020 4:11 PM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Cc: Adam, Stacey (FNIH) [T] < (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) >; Appell, Evan < (b) (6) >
Subject: FW: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Ashley,

Please see below a question from Neil. My understanding is it will be a feature once it's live on the website is that correct? Please feel free to provide any additional information / clarification that would help address Neil's inquiry. Thank you!

Warm regards,
Helen

-----Original Message-----

From: Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6) >
Sent: Wednesday, September 9, 2020 4:07 PM
To: Chen, Helen Q. < (b) (6) >
Subject: [EXT] RE: ACTIV Therapeutics-Clinical Working Group Meeting

Thanks Helen. This has the potential to be a really useful document. At this point, should we be able to see agent information if we hover over the black circle with an A in it? If so, that feature does not seem to be working (at least not for me).

Best,
Neil

Neil Aggarwal, MD
Chief, Lung Biology and Disease Branch
Division of Lung Diseases / NHLBI / NIH

-----Original Message-----

From: Chen, Helen Q. < (b) (6) >
Sent: Wednesday, September 9, 2020 1:27 PM
To: Adam, Stacey (FNIH) [T] < (b) (6) >; Bozzette, Sam (NIH/NCATS) [E] < (b) (6) >
Butterton, Joan < (b) (6) >; De Claro, R. Angelo (FDA/CDER) < (b) (6) >
Draghia-Akli, Ruxandra < (b) (6) >; Eisner, Mark < (b) (6) >; Gottesdiener, Keith < (b) (6) >
< (b) (6) >; Eric Hughes < (b) (6) >; Judy Currier < (b) (6) >
< (b) (6) >; Kim, Elizabeth < (b) (6) >; LaVange, Lisa < (b) (6) >

Levy, Elliot < (b) (6) Mellors, John W < (b) (6) Menon, Sandeep
 < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Patel, Nainish
 < (b) (6) Peppercorn, Amanda < (b) (6) Poole, Mike
 < (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) >; Read, Sarah
 (NIH/NIAID) [E] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Shen, Yuan Li
 (FDA/CDER) < (b) (6) Stein, Peter (FDA/CDER) < (b) (6) Wholley, David
 (FNIH) [T] < (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) Collins, Sylva
 (FDA/CDER) < (b) (6) Amanda Peppercorn <amanda. (b) (6) Garner, Carl
 < (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) Koroshetz, Walter
 (NIH/NINDS) [E] < (b) (6) Timothy Burgess < (b) (6) Reineck, Lora
 (NIH/NHLBI) [E] < (b) (6) Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6)
 Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E]
 < (b) (6) Brown, Jeremy (NIH/NINDS) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E]
 < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) Jacqueline Kirchner
 < (b) (6) Beidel, John (NIH) [E] < (b) (6) Phillips, L
 Revell CIV DTRA RD (USA) < (b) (6) Petrovick, Martha - 0449 - MITLL
 < (b) (6) Sizemore, Christine (NIH/FIC) [E]
 < (b) (6)
 Cc: Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy
 < (b) (6) Jansen, Kathrin < (b) (6) Kurilla, Michael
 (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI) < (b) (6) Young, John
 < (b) (6) Biggs, Mary < (b) (6) Butcher, Tina < (b) (6)
 Demarcus < (b) (6) Macone, Erin < (b) (6) Melencio, Cheryl (FNIH) [T]
 < (b) (6) Salathin, Carla < (b) (6) Tountas, Karen (FNIH) [T]
 < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) James, Stephanie (FNIH) [T]
 < (b) (6) Wachtel, Jonathan < (b) (6) btolman < (b) (6) Alvarez,
 Rosa Maria < (b) (6) Gonzalez, Nina < (b) (6) Dana Carluccio
 < (b) (6) Rose Li Central Account < (b) (6) Margaret
 Anderson < (b) (6) Lucas Smalldon < (b) (6) Stratton,
 Benjamin < (b) (6)
 < (b) (6) Oashu, Felicia (NIH/OD) [E] < (b) (6) Mollica, Linda /US
 (NIH/NHLBI) [E] < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Patterson, Amy
 Hilary (NIH/NIAID) [E] < (b) (6) Wung, Peter /US < (b) (6) Marston,
 (NIH/NHLBI) [E] < (b) (6) Groesch, Mary (NIH/NHLBI) [E] < (b) (6) Hoots, W. Keith
 Allan (NIH/NHLBI) [E] < (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E]
 < (b) (6) Hone, David M (Dave) CIV DTRA J9 (USA) < (b) (6) Shipp,
 Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) < (b) (6) Freire, Maria (FNIH)
 [T] < (b) (6) Elsaid, Olivia < (b) (6) Appell, Evan < (b) (6)
 Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported COVID-19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards,
 Stacey, Mike, and Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] < (b) (6)
 Sent: Wednesday, June 17, 2020 8:48 AM
 To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butters, Joan; De Claro, R. Angelo
 (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim,
 Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E];
 Patel, Nainish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah
 (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley,
 David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn;
 Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess;
 Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff,
 David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle
 (NIH/OD) [E]; Jacqueline Kirchner; Beidel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA);
 Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]
 Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS)
 [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio,
 Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James,
 Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana
 Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin;
 (b) (6) Mollica, Linda /US; Oashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI)
 [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US;
 Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski,
 Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO
 CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
 Subject: ACTIV Therapeutics-Clinical Working Group Meeting

When: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC 05:00) Eastern Time (US & Canada).
Where: <https://secure-web.cisco.com/1>

(b) (6)

(b) (6)

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
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Meeting ID: (b) (6)

Password: (b) (6)

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US (Germantown)

US (Chicago)

Dial by your location

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32 US (Germantown)

39 US (Chicago)

23 US (New York)

32 US (Tacoma)

39 US (Houston)

38 US (San Jose)

33 US (San Jose)

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From: Wachtel, Jonathan I (b) (6)]
Sent: 5/22/2020 2:27:53 PM
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CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: FW: ACTIV Clinical Trial Capacity survey dashboard

Michelle/Ellen

Access granted. Please find the link below.

Best,

Jonathan Wachtel
Deloitte Consulting LLP
Tel/Direct: (b) (6)
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From: Tountas, Karen (FNIH) [T] < (b) (6) >
Sent: Wednesday, May 20, 2020 4:13 PM
To: Bascles, Lionel < (b) (6) > Cohen, Myron < (b) (6) > Corey, Larry < (b) (6) >
< (b) (6) > Victoria Davey < (b) (6) > Desrosiers, Betsy < (b) (6) >
< (b) (6) > Dickens, Jim (NIH/NCATS) [C] < (b) (6) > Doroshov, James (NIH/NCI) [E] < (b) (6) >
< (b) (6) > Garner, Carlos < (b) (6) > Goff, David (NIH/NHLBI) [E] < (b) (6) >
< (b) (6) > Kurilla, Michael (NIH/NCATS) [E] < (b) (6) > Mensah, George (NIH/NHLBI) [E] < (b) (6) >
< (b) (6) > Nayak, Seema (NIH/NIAID) [E] < (b) (6) > Payton, Manizhe (NIH/NIAID) [E] < (b) (6) >
< (b) (6) > Resnansky, Laura < (b) (6) > Sizemore, Christine (NIH/FIC) [E] < (b) (6) >
< (b) (6) > Srinivasan, Badhri < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) >
< (b) (6) > Vincent, Mike < (b) (6) > Weinmann, Gail (NIH/NHLBI) [E] < (b) (6) >
Cc: Wachtel, Jonathan < (b) (6) > Footer, Kevin < (b) (6) > Jones, Ethan < (b) (6) >
< (b) (6) > Long, Alyssa < (b) (6) >
Subject: [EXT] ACTIV Clinical Trial Capacity survey dashboard
Importance: High

Dear Colleagues,

BLUF*: The ACTIV Clinical Trial Capacity survey dashboard is ready for use

Caveat Now for those with NIH credential and in a few days for those external to the NIH system

After several unforeseen technical issues with both the data and the infrastructure, the clinical network and site the dashboard is ready for use. A big thank you to Jonathan and Kevin and the team at Deloitte for putting this dashboard together. We're not letting them off the hook that easily – they already are working on incorporating the CRO-SMO survey data.

For those of you with NIH credentials, you will be able to access the dashboard through this link:

<https://analyticsqa.niaid.nih.gov/#/site/ACTIV-views/ACTIVCTCWGSurveyDashboard/NetworkSiteMap?rid=1>. You will find four tabs at the top of the page: 1) Network Site Map, a dashboard with the map (sites and COVID-19 data, by USA with county-level data or world wide, country-level views) and the network and site filters, 2) Network Detail Dashboard, a one-page summary of the network based on the survey responses, 3) Glossary, a few definitions that we have been using; and, 4) Resources that might be of interest. I have poked around the dashboard a bit – use is fairly

intuitive, but if you have questions please feel free to reach out to Kevin, Ethan, or Alyssa (copied on this email). However, please note that the dashboard is "hot off the press" so if you notice any issues with the dashboard, or would like to pass along thoughts that might improve the user experience, please bring them to the attention of Kevin, Ethan, or Alyssa.

The team is working on getting everyone else on the WG access, targeting the end of this week. Apparently, this has proved a bit more challenging for the NIH group that hosts this platform than anticipated

As you all know,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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 [(b) (6) Tolman, Brett [(b) (6)

Attachments: Clinical Trial Capacity Working Group Meeting Agenda_04212020.pdf

Location: <https://zoom.us/> (b) (6)

Start: 4/21/2020 1:00:00 PM

End: 4/21/2020 2:00:00 PM

Recurrence: (none)

Required Attendees: Bascles, Lionel; Srinivasan, Badhri; Vincent, Mike; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Woodcock, Janet (FDA/CDER)

Optional Attendees: Santos, Michael (FNIH); Hamilton, Nancy; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana, Cheryl (FNIH); Melencio [T] (b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6) Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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To: Draghia-Ak I, Ruxandra [(b) (6)] Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fid]; Eisner, Mark [(b) (6)] Gottesdiener, Keith [(b) (6)] Judy Curner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)] LaVange, Lisa [(b) (6)] Levy, Elliot [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [(b) (6)] Peppercorn, Amanda [(b) (6)] Poole, Mike [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [(b) (6)] Garner, Carl [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6)] Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

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CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Salathin, Carla | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) Tolman, Brett | (b) (6) Alvarez, Rosa | (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio | (b) (6) Rose Li Central Account | (b) (6) Anderson, Margaret | (b) (6) Lucas Smalldon | (b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. | (b) (6) Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; K ndzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) | (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Eisaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]

Subject: Canceled: ACTIV Therapeutics-Clinical Working Group Meeting

Location: <https://fnih.zoom.us/> (b) (6)

Start: 8/20/2020 5:00:00 PM

End: 8/20/2020 6:00:00 PM

Show Time As: Free

Recurrence: Weekly

every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Draghia-Akli, Ruxandra; Butters, Joan; Hughes, Eric; Bozzette, Sam (NIH/NCATS) [E]; De Claro, R. Angelo (FDA/CDER); Eisner, Mark; Gottesdiener, Keith; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Namish; Peppercorn, Amanda; Poole, Mike; Prosch, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylvia (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6); Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

(b) (6) Sizemore, Christine (NIH/FIC) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathryn; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Car a; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose L Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Kerth (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kndzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia

Dear ACTIV TX-Clinical WG,

we were unable to find a suitable time to reschedule this week's meeting for to accommodate our presenters. Therefore, we will just cancel for this week. Please enjoy the neutralizing Ab Summit on Thursday!

Thanks,
Stacey

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 [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364];
 Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];
 Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike
 [(b) (6) Proschan, Michael (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange
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 Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Garner, Carl [(b) (6) Koroshetz, Walter (NIH/NINDS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner
 [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV
 DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6)
 (b) (6)
 CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Kurilla, Michael (NIH/NCATS)
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Tountas, Karen (FNIH) [T]
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Gonzalez, Nina [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Bethany Stokes [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis];
Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon [(b) (6) Stratton, Benjamin [(b) (6) (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)
CIV DTRA J9 (USA) (b) (6)

Attachments: ACTIV TX-Clinical_Working Group Meeting Guide 20200716.pdf

Start: 7/16/2020 5:00:00 PM
End: 7/16/2020 6:00:00 PM

Recurrence: (none)

Required Attendees: Higgs, Elizabeth (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschian, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylvia (FDA/CDER); Amanda Peppercorn; Garner, Carl; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6)
Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L. Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

(b) (6)

Optional Attendees: Bethany Stokes; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon, Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Alan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA)

Dear ACTIV TX-Clinical WG,

Please find attached the slides with the agenda for today's meeting. As requested, we will be receiving an update from the Vaccine's WG as part of the meeting today.

Thanks,
Stacey

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To: Bozzette, Sam (NIH/NCATS) [E] [(b) (6)]; De Claro, R. Angelo (FDA/CDER) [(b) (6)]; Eric Hughes [(b) (6)]; Judy Currier [(b) (6)]

[(b) (6) Mellors, John W [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [(b) (6)] Read, Sarah (NIH/NIAID) [E] [(b) (6)]; Santos, Michael (FNIH) [T] [(b) (6)] Shen, Yuan Li (FDA/CDER) [Yuan. (b) (6)]; Stein, Peter (FDA/CDER) [(b) (6)] Wholley, David (FNIH) [T] [dwholley@fnihi.org]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6)] Collins, Sylva (FDA/CDER) [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6)] Koroshetz, Walter (NIH/NINDS) [E] [(b) (6)]; Timothy Burgess [(b) (6)] Reineck, Lora (NIH/NHLBI) [E] [(b) (6)]; Aggarwal, Neil (NIH/NHLBI) [E] [(b) (6)] Rosenberg, Yves (NIH/NHLBI) [E] [(b) (6)] Goff, David (NIH/NHLBI) [E] [(b) (6)] Brown, Jeremy (NIH/NINDS) [E] [(b) (6)] Gadbois, Ellen (NIH/OD) [E] [(b) (6)] Culp, Michelle (NIH/OD) [E] [michelle.culp@nih.gov]; Beigel, John (NIH) [E] [(b) (6)] Sizemore, Christine (NIH/FIC) [E] [(b) (6)] Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Garner, Carl [(b) (6)] Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)] Gottesdiener, Keith [(b) (6)] Eric Hughes [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)] LaVange, Lisa [(b) (6)] Levy, Elliot [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)] Peppercorn, Amanda [(b) (6)] Poole, Mike [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva Coll]; Amanda Peppercorn [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcb847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves

(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Larry Tsai
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[(b) (6)
Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Lowy, Douglas (NCI) [(b) (6) Melencio, Cheryl
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[(b) (6) Marston, Hilary (NIH/NIAID) [E] (b) (6) ; Chen, Helen Q.
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[(b) (6) Shipp, Allan (NIH/NHLBI) [E] [allan. (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E]
[(b) (6) Walker, Paula (NIH/NINDS) [E] [(b) (6) Sorosa, Alex David
[(b) (6) Lumsden, Joanne (NIH/NCATS) [C] (b) (6)]; Embry, Alan (NIH/NIAID) [E]
[(b) (6) Lerner, Andrea (NIH/NIAID) [E] [(b) (6) Lerner, Andrea (NIH/NIAID) [E]
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[(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon
[(b) (6) Mollica, Linda /US
[(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)

CC:

CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
(b) (6) (b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Embry, Alan (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

Attachments: ACTIV_TX-Clinical WG Meeting_20210128_v2.pdf

Start: 1/28/2021 6:00:00 PM

End: 1/28/2021 7:00:00 PM

Recurrence: (none)

Required Attendees: Garner, Carl; Bozette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John, Menon, Sandeep Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael, Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Naumova, Anna; Hochman, Judith

Optional Attendees: Lerner, Andrea (NIH/NIAID) [E]; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Meencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Alan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA), Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex David, Lumsden, Joanne (NIH/NCATS) [C]; Embry, Alan (NIH/NIAID) [E]

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 6/11/2020 7:52:02 PM

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Sandeep Menon [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6) d (b) (6) MHUGHES@SDAC.HARVARD.EDU; (b) (6) (b) (6) william_fischer@med.unc.edu; Eron, Joe (b) (6) Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]

CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6) Eron, Joseph J Jr (b) (6) Smith, David [(b) (6) Paul Klekotka [(b) (6) Ajay Nirula [(b) (6) Chen, Helen Q. [(b) (6)]

Subject: Canceled: HOLD for Potential ACTIV-2 Writing Team Meeting - Review of FDA Comments

Location: <https://fnih.zoom>. (b) (6)

Start: 6/18/2020 4:00:00 PM

End: 6/18/2020 5:00:00 PM

Show Time As: Free

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6) (b) (6) (b) (6) (b) (6) william_fischer@med.unc.edu; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6) Kim, Peter (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Erhardt, William (OS/ASA/OCIO/DCIO-Ops) (CTR)

Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

Dear ACTIV-2 Writing Team,

We have not yet received the FDA comments expected this morning. Therefore, in the interest of making best use of everyone's time, we will be working with Davey and Judy to find a time to reschedule over the next couple of days. We will be in touch as soon as we have a time.

Thanks,

Stacey

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Meeting ID: (b) (6) 4

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 1/12/2021 9:50:24 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] (b) (6); Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [(b) (6) Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Victoria Davey [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [(b) (6) Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Johnson, Robert (OS/ASPR/BARDA) [(b) (6) Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [(b) (6)]; Mascola, John (NIH/VRC) [E] [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Pandya, Hitesh [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [rplenge@celgene.com]; Plump, Andy [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Stoffels, Paul [(b) (6)]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Tal ey, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6)]; Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Woodcock, Janet (FDA/CDER) [(b) (6) Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Anderson, James (NIH/OD) [E] [(b) (6) Burklow, John (NIH/OD) [E] [(b) (6) Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6)]; Lumsden, Joanne (NIH/NCATS) [C] [(b) (6)]; Myles, Renate (NIH/OD) [E] [(b) (6) Wolinetz, Carrie (NIH/OD) [E] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Margaret Anderson [(b) (6) Appell, Evan [(b) (6) Chen, Helen [(b) (6) Connelly, Sarah [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6)]; Mendelson, Jesse [(b) (6) Nasr, Hana [(b) (6) Sorosa, Alex [(b) (6) Stratton, Benjamin [(b) (6) btolman [(b) (6) Wachtel, Jonathan [(b) (6) Meltzer, Abbey (FNIH) [T] [(b) (6) Embry, Alan (NIH/NIAID) [E] [(b) (6)], Bancel, Stephane [(b) (6) Meeker, David [(b) (6) Pangalos, Mene [(b) (6) Paul, Steve [(b) (6) Rachel Ramoni [(b) (6) Togashi, Mieko (NIH/NCI) [E] [(b) (6) .gov]; Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Carver, Trea (NIH) [C] [(b) (6) Hughes, Karen (NIH/OD) [E] [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Magbie-Robinson, Kim (NIH/OD) [C] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Austin, Sarah (NIH/NIAID) [E] [(b) (6) Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Bell, Julie [(b) (6) Caulfield, Anita [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [(b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6) Edl, Susan [(b) (6)]; Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [(b) (6) Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Lever, Susan [(b) (6) Martin, Melisa [(b) (6) McManus, Ayanna (NIH/OD) [E] [(b) (6) Minnich, Beth [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riggins, Mary [(b) (6)

(b) (6)	Ripley, Nadege [(b) (6)	Schuster, Donna
(b) (6)	Sepulveda, Dorina (FNIH) [T]	(b) (6)	; Suhana, Tina (NIH/VRC) [E]
(b) (6)]; Thomas, Ashley (FDA/CDER) [(b) (6)]; Wood, Gretchen (NIH/OD) [E]
(b) (6)	Regan, Donna M [(b) (6)	Vessey, Rupert [
Lowy, Douglas (NIH/NCI) [E]	(b) (6)		(b) (6)

Subject: ACTIV Leadership Team Call #13

Location: <https://fnih.zoom.us/> (b) (6)

Start: 2/17/2021 4:30:00 PM

End: 2/17/2021 6:00:00 PM

Show Time As: Busy

Required Attendees: Melencio, Cheryl (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavalen, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, El en (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathryn; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NIH/NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Meltzer, Abbey (FNIH) [T]; Embry, Alan (NIH/NIAID) [E]

Optional Attendees: Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Magbie-Robinson, Kim; Simon, Dina (NIH/OD) [C]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Varde; Jenkins, Christine S.; Krack, Kimberly; Lever, Susan; Martin, Melissa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Regan, Donna M; Vessey, Rupert; Lowy, Douglas (NIH/NCI) [E]

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Penny Heaton [(b) (6)]
Sent: 5/14/2020 10:40:17 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak], Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Dear All,

Yes – I agree to be listed on the web site as part of the ACTIV team.

Best,

Penny

Penny M. Heaton, MD
Chief Executive Officer
Bill & Melinda Gates Medical Research Institute
245 Main Street, Cambridge, MA 02142
T (b) (6) M (b) (6)
E (b) (6)

Mary Burke
Executive Assistant to the CEO
Bill & Melinda Gates Medical Research Institute
245 Main Street, Cambridge, MA 02142
M (b) (6)
E (b) (6)

From: Collins, Francis (NIH/OD) [E] < (b) (6) >
Sent: Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Cc: Myles, Renate (NIH/OD) [E] < (b) (6) > Meltzer, Abbey (FNIH) [T] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) >
Subject: Time sensitive: Making your ACTIV Participation Public

Attention: This message was sent from an external domain.

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please**

send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/18/2020 2:26:39 PM
To: (b) (6) Tomas Cihlar [(b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US [(b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael

[(b) (6) Rose Li [(b) (6) Dana Carluccio
[(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos];
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) Florence, Clint (NIH/NIAID) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Louise Pitt
((b) (6) [(b) (6) Hild, Shen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]
Subject: RE: ACTIV Preclinical working group (Friday meeting)
Attachments: ACTIV PRECLINICAL Animal Model inventory 20200514 ipm.xlsx; Therapeutic information request form-v8.docx;
2020-05-15 Precinical WG Summary d4.docx

[Confidential and Pre-decisional]

Dear Preclinical working group members and invitees,

Thank you for a very interesting meeting on Friday. Please find the attached minutes for your review. Also, I am attaching the current therapeutic information request and the animal model inventory. Finally I have pasted the action items below.

Best regards,
Joe

Action Items:

- Dr. Jay Rappaport will share a white paper to ACTIV leadership outlining the necessary responsibilities of an NPRC coordinating group.
- Joe will share the newest version of the therapy request form to the WG after making the changes discussed. [with this email]
- Joe will send members the most recent WG animal model inventory. [with this email]
- Dr. Srinivas Rao will lead the WG in developing IP protection strategies by generating a first draft of the topics that need to be addressed.
- Dr. Rappaport will share guidelines on how the NPRCs enable academic researchers to publish data derived from research that uses IP.

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:48 PM

To: (b) (6) Tomas Cihlar; (b) (6) Menetski, Joseph (FNIH) [T];

(b) (6) (b) (6) (b) (6) (b) (6)

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(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis

(NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James

(NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]

Cc: Nancy Haigwood; Lowy, Douglas (NIH/NCI) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin,

Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D, Dave Frankowski; Florence, Clint (NIH/NIAID) [E]; Louise Pitt (b) (6) Hid, Sheri (NIH/OD) [E]

Subject: ACTIV Preclinical working group (Friday meeting)

When: Friday, May 15, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom>. (b) (6)

Holding time

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/2/2020 7:38:15 PM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6) .com]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Na mish Patel (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskip]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Follow-up to ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #6
Attachments: 2020-05-01- TX Clinical WG_Agent Prioritization_Sub-WG Summary RLA.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

I hope you are all doing well today! I know for some of you the pull of the great weather is likely strong to go outside! I hope that you are able to do so despite our scoring task!

Just a quick reminder; please have your score sheets to me by 12pm US ET tomorrow (Sunday, May 3).

In addition, please find attached the summary of yesterday's meeting. Let me know if you have any additions or amendments that you think are critical.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

Direct: (b) (6) | Mobile: (b) (6)

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]

Sent: 11/12/2020 5:10:27 PM

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] (b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [(b) (6) Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [(b) (6)]; Erck, Stan [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Johnson, Robert (OS/ASPR/BARDA) [(b) (6) Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Marks, Peter (FDA/CBER) [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6) Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Messonnier, Nancy [(b) (6) Pandya, Hitesh [(b) (6) Parker, Ashley [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Rachel Ramoni [(b) (6)]; Rasi, Guido [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Tal ey Michael [(b) (6) Vessey, Rupert [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Woodcock, Janet (FDA/CDER) [(b) (6) Young, John [john. (b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Victoria Davey [(b) (6) Villafana, Tonya [(b) (6) Bancel, Stephane [(b) (6) Fauci, Anthony [(b) (6) (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lepore, John [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Paul, Steve [(b) (6) Plump, Andy [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Tsai, John [(b) (6) (b) (6) Anderson, James (NIH/OD) [E] [(b) (6)], Burklow, John (NIH/OD) [E] [(b) (6) Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6) Myles, Renate [(b) (6) (NIH/OD) [E] [(b) (6) .gov]; Wolinetz, Carrie (NIH/OD) [E] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Margaret Anderson [(b) (6) Appell, Evan [(b) (6) Chen, Helen Q. [(b) (6) Connelly, Sarah [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6)]; Mendelson, Jesse [(b) (6) m]; asorosa [(b) (6) Stratton, Benjamin [(b) (6) btolman [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6) Gorman, Greta (FNIH) [T] [(b) (6) Meltzer, Abbey (FNIH) [T] [(b) (6) Austin, Sarah (NIH/NIAID) [E] [(b) (6) Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Bell, Julie [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Carver, Trea (NIH) [C] [(b) (6) Caulfied, Anita [(b) (6) Coan, Amanda [(b) (6)]; Conrad, Patricia (NIH/NIAID) [E] [(b) (6)]; Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6)]; Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoffstetter, Renata (FNIH) [T] [(b) (6) Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6)]; Lever, Susan [(b) (6) McManus, Ayanna (NIH/OD) [E] [(b) (6) Minnich, Beth [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riggins, Mary [(b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Sepulveda, Dorina (FNIH) [T] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6)]

[(b) (6) Suhana, Tina (NIH/VRC) [E] [(b) (6)]; Thomas, Ashley (FDA/CDER)
 [(b) (6)]; Wood, Gretchen (NIH/OD) [E] [(b) (6) Hughes, Karen (NIH/OD) [E]
 [(b) (6)]; Tajalli, Ada (NIH/OD) [E] [(b) (6)]; Togashi, Meko (NIH/NCI) [E]
 [(b) (6)]; Underwood, Nancy [(b) (6) Zottoli, Jessica
 [(b) (6) Vessey, Rupert [(b) (6) Regan, Donna M
 [(b) (6) Grant, Sarah [(b) (6) Plenge, Robert [(b) (6)
 Lowy, Douglas (NIH/NCI) [E] [(b) (6) Nasr, Hana [(b) (6) Hoban, Michelle
 [(b) (6)

Subject: ACTIV Leadership Team Meeting #11

Location: <https://fnih.zoom.us/> (b) (6)

Start: 12/16/2020 3:00:00 PM

End: 12/16/2020 4:30:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauc, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; G bbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E] Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ash ey (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Ras, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilia, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Victoria Davey; (b) (6) Villafana, Tonya

Optional Attendees: Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appel, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Tajalli, Ada (NIH/OD) [E]; Togashi, Meko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Vessey, Rupert; Regan, Donna M; Grant, Sarah; Plenge, Robert; Lowy, Douglas (NIH/NCI) [E]; Nasr, Hana

Extending the call by 30 minutes per discussion at Nov. 19 Leadership Team call

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Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us>, (b) (6)

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/24/2020 4:46:07 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [austinc@mail.nih.gov]; Collins, Francis (NIH/OD) [E] [collinsf@od.nih.gov]; Corey, Larry [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [(b) (6) Hudson, Thomas [(b) (6) m]; James, Stephanie (FNIH) [T] [(b) (6) Johnson, Robert (OS/ASPR/BARDA) [(b) (6) Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Marks, Peter (FDA/CBER) [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6) Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plump, Andy [(b) (6) Rasi, Guido [(b) (6) Reed, John [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) i]; Stoffels, Paul [(b) (6) .com]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Woodcock, Janet (FDA/CDER) [(b) (6) Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Freire, Maria (FNIH) [T] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Gonzalez, Nina [(b) (6) Kim, Elizabeth [(b) (6) Stratton, Ben [(b) (6) Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6) Rachel Ramoni [(b) (6) Plenge, Robert [(b) (6) Talley, Michael [(b) (6) Cavaleri, Marco [(b) (6) Messonnier, Nancy [(b) (6) G bbons, Gary (NIH/NHLBI) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6)]; Culp, Michelle (NIH/OD) [E] [(b) (6)]; Tsai, John [(b) (6)]
CC: Barasch, Kimberly (NIH/NIAID) [C] [(b) (6)]; Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Carver, Trea (NIH) [C] [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [(b) (6) .gov]; Hoffstetter, Renata (FNIH) [T] [(b) (6)]; Iberdemaj, Vaide [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6)]; McManus, Ayanna (NIH/OD) [E] [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Protasiewicz, Ann [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Thomas, Ashley (FDA/CDER) [(b) (6) Wood, Gretchen (NIH/OD) [E] [(b) (6) Sepulveda, Dorina (FNIH) [T] [(b) (6) FNIH Central Account [(b) (6) Li, Rose [(b) (6) Zottoli, Jessica [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Gladman, Jordan (NIH/OD) [E] [(b) (6) Elsaid, Olivia [(b) (6) Castillejos zenteno, Carlos [JRDUS] [(b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6) Burklow, John (NIH/OD) [E] [(b) (6) Wolinetz, Carrie (NIH/OD) [E] [(b) (6) Myles, Renate (NIH/OD) [E] [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6) Chen, Helen [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) Meltzer, Abbey (FNIH) [T] [(b) (6) Gorman, Greta (FNIH) [T] [(b) (6) Dana Carluccio [(b) (6) .com]

Subject: ACTIV Response Partnership Leadership Team Meeting #4
Location: <https://fnih.zoom.us/j> (b) (6)
Start: 6/3/2020 4:00:00 PM
End: 6/3/2020 5:30:00 PM
Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Dons; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsa, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; To man, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramon; Plenge, Robert; Talley, Michael; (b) (6) Cavaleri, Marco; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Gibbons, Gary (NIH/NHLBI) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Treva (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Me encio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; FNIH Central Account; Li, Rose; Zottoli, Jessica; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Castillejos zenteno, Carlos (JRDUS); Dimishkov, Roxanne (NIH/NHLBI) [C]; Burklow, John (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Chen, Helen; Lowy, Douglas (NIH/NCI) [E]; Meltzer, Abbey (FNIH) [T]; Gorman, Greta (FNIH) [T]; Dana Carluccio

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 4:14:59 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fid]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesd ener, Keith [(b) (6) Hughes, Eric [(b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel];
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
 (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
 Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
 [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
 (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6)
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose
 Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas
 Smalldon [(b) (6) Stratton, Benjamin [(b) (6)
 (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

Subject: ACTIV TX-C inical Working Group Meeting #7
Attachments: ACTIV Therapeutics-Clinical Full Working Group 21May2020 Meeting Guide.pdf
Location: <https://fnih.zoom.us/> (b) (6)

Start: 5/21/2020 6:00:00 PM
End: 5/21/2020 7:00:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER), Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith, Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep, Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E], Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]
Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Jansen, Kathrin; Kunlla, Michael (NIH/NCATS) [E], Lowy, Douglas (NCI), Young, John, Biggs, Mary, Butcher, Tina, Demarcus; Macone, Erin, Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett, Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose L. Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Rubin, Daniel B. (FDA/CDER)

Dear ACTIV TX-Clinical WG,

Looking forward to seeing you all soon at the meeting. Please find attached the slides for the meeting.

Thanks,
 Stacey

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/15/2020 10:23:11 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: Materials for July 15 ACTIV Executive Committee Teleconference
Flag: Follow up

I told him it was lovely of him to ask and that I'd let you know.

From: Pao, William <william. (b) (6)>
Sent: Wednesday, July 15, 2020 4:37 PM
To: Wholley, David (FNIH) [T] < (b) (6)>
Subject: RE: Materials for July 15 ACTIV Executive Committee Teleconference

Hi David,
I meant to ask at the end -- for fear of jumping into the political fray, is there anything we can do to support Tony?
Best,
William

From: Melencio, Cheryl (FNIH) [T] (b) (6) **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Wednesday, July 15, 2020 2:44 AM
To: Collins, Francis (NIH/OD) [E] < (b) (6)>; Disbrow, Gary (OS/ASPR/BARDA) (b) (6)
Dolsten, Mikael (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] < (b) (6)>; Gibbons, Gary (NIH/NHLBI) [E] (b) (6) >; Marks, Peter (FDA/CBER) (b) (6) >; Pao, William (b) (6) >; Plump, Andrew < (b) (6)>; Stoffels, Paul (b) (6)
Woodcock, Janet (FDA/CDER) (b) (6) >; Colvis, Christine (NIH/NCATS) [E] (b) (6) >; Desrosiers, Betsy (b) (6) >; Eric Hughes < (b) (6)>; Jansen, Kathrin (b) (6) >; Kurilla, Michael (NIH/NCATS) [E] < (b) (6)>; Lowy, Douglas (NCI) (b) (6) >; Read, Sarah (NIH/NIAID) [E] (b) (6)
Young, John <j. (b) (6)>
Cc: Anderson, James (NIH/OD) [E] (b) (6) >; Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Burklow, John (NIH/OD) [E] < (b) (6)>; Castillejos, Carlos < (b) (6)>
Culp, Michelle (NIH/OD) [E] (b) (6) >; FNIH Central Account (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) >; Gadbois, Ellen (NIH/OD) [E] (b) (6) >; Hallett, Adrienne (NIH/OD) [E] < (b) (6)>; Lane, Cliff (NIH/NIAID) [E] < (b) (6)>; Myles, Renate (NIH/OD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Wolinetz, Carrie (NIH/OD) [E] <ca (b) (6)>; Adam, Stacey (FNIH) [T] < (b) (6)>; Alvarez, Rosa (b) (6) >; Anderson, Margaret (b) (6)
Chen, Helen (b) (6) >; Elsaid, Olivia (b) (6) >; Gonzalez, Nina (b) (6) >; James, Stephanie (FNIH) [T] < (b) (6)>; Menetski, Joseph (FNIH) [T] (b) (6) >; Santos, Michael (FNIH) [T] (b) (6) >; Stratton, Ben < (b) (6)>
Tolman, Brett (b) (6) >; Tountas, Karen (FNIH) [T] (b) (6) >; Wachtel, Jonathan (b) (6) >; Wholley, David (FNIH) [T] (b) (6) >; Gorman, Greta (FNIH) [T] (b) (6) >; Meltzer, Abbey (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6)
Subject: Materials for July 15 ACTIV Executive Committee Teleconference

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 PM to 4:30 PM Eastern U.S. time tomorrow, Wednesday July 15. I have also attached notes from our July 1 Leadership Team meeting as well as our last EC meeting on June 17.

The Zoom meeting information is:

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Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: LaVange, Lisa M [(b) (6)]
Sent: 4/29/2020 5:37:40 PM
To: Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Judy Currier [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) (b) (6) Amanda Peppercorn [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Far ey, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6)
CC: Mary Biggs [(b) (6) DeMarcus, Forrest [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Has ACTT1 been stopped?

Thanks, Mike. This is great news!

From: Proschan, Michael (NIH/NIAID) [E] [mailto: (b) (6)]
Sent: Wednesday, April 29, 2020 1:35 PM
To: Adam, Stacey (FNIH) [T] < (b) (6) > Bozzette, Sam (NIH/NCATS) [E] < (b) (6) > Butterton, Joan < (b) (6) > Collins, Sylvia (FDA/CDER) < (b) (6) > Judy Currier < (b) (6) > De Claro, R. Angelo (FDA/CDER) < (b) (6) > Mark Eisner < (b) (6) > Keith Gottesdiener < (b) (6) > Eric Hughes < (b) (6) > LaVange, Lisa M < (b) (6) > Elliott Levy < (b) (6) > Sandeep Menon < (b) (6) > Amanda Peppercorn < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Amanda Peppercorn < (b) (6) > Price, Dionne

(FDA/CDER) < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Shen, Yuan Li
 (FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Goff, David (NIH/NHLBI)
 [E] < (b) (6) Vincent, Michael < (b) (6) Wung, Peter /US
 <Peter. (b) (6)
Cc: Mary Biggs < (b) (6) DeMarcus, Forrest < (b) (6) Macone, Erin
 < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan < (b) (6)
 Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Butcher, Tina
 < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T]
 < (b) (6)

Subject: RE: Has ACTT1 been stopped?

The trial has accrued its target number of patients and recoveries, so this is not really an "interim" result. The DSMB recommended releasing the data to the NIH, and Dr. Fauci just announced preliminary results today. Follow up of all patients to at least 28 days will continue, but results will not change appreciably. Remdesivir was statistically significantly superior to placebo in terms of the primary endpoint, time to recovery. More detailed results will be coming soon.

Mike

From: Adam, Stacey (FNIH) [T] < (b) (6)
Sent: Wednesday, April 29, 2020 1:27 PM
To: Bozzette, Sam (NIH/NCATS) [E] < (b) (6) Butterson, Joan <joan (b) (6) Collins,
 Sylva (FDA/CDER) < (b) (6) Judy Currier < (b) (6) De Claro, R. Angelo
 (FDA/CDER) < (b) (6) Mark Eisner < (b) (6) Keith Gottesdiener
 < (b) (6) Eric Hughes < (b) (6) LaVange, Lisa M < (b) (6)
 Elliott Levy < (b) (6) Sandeep Menon < (b) (6) Amanda Peppercorn
 < (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah
 (NIH/NIAID) [E] < (b) (6) Amanda Peppercorn < (b) (6) Price, Dionne
 (FDA/CDER) < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Shen, Yuan Li
 (FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Goff, David (NIH/NHLBI)
 [E] < (b) (6) Vincent, Michael < (b) (6) Wung, Peter /US
 < (b) (6)
Cc: Mary Biggs < (b) (6) Demarcus < (b) (6) Macone, Erin < (b) (6)
 Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan < (b) (6) Elizabeth Kim
 < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Butcher, Tina
 <tina (b) (6) Wholley, David (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T]
 < (b) (6)

Subject: RE: Has ACTT1 been stopped?

Hi Sam,

DSMB was this week to review interim results, though the trial has fully accrued, so the interim may quickly transition to final. However, we were only expecting some blinded results to point us in the right direction next week. I will let Michael or others weigh in if my understanding was in correct.

Thanks,
 Stacey

Stacey J. Adam, PhD
 Director, Cancer
 Research Partnerships
 Direct: (b) (6) Mobile: (b) (6)

From: Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>
Sent: Wednesday, April 29, 2020 1:22 PM
To: Adam, Stacey (FNIH) [T] <(b) (6)> Butterson, Joan <joan (b) (6)> Collins, Sylva
 (FDA/CDER) <(b) (6)> Judy Currier <(b) (6)> De Claro, R. Angelo (FDA/CDER)
 <(b) (6)> Mark Eisner <(b) (6)> Keith Gottesdiener
 <(b) (6)> Eric Hughes <(b) (6)> LaVange, Lisa M <(b) (6)>
 Elliott Levy <(b) (6)> Sandeep Menon <(b) (6)> Amanda Peppercorn
 <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah
 (NIH/NIAID) [E] <(b) (6)> Amanda Peppercorn <(b) (6)> Price, Dionne
 (FDA/CDER) <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Shen, Yuan Li
 (FDA/CDER) <(b) (6)> Farley, John (FDA/CDER) <(b) (6)> Goff, David (NIH/NHLBI)
 [E] <(b) (6)> Vincent, Michael <(b) (6)> Wung, Peter /US
 <(b) (6)>
Cc: Mary Biggs <(b) (6)> Demarcus <(b) (6)> Macone, Erin <(b) (6)>
 Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Elizabeth Kim
 <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Butcher, Tina
 <tina (b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T]
 <(b) (6)>
Subject: Has ACTT1 been stopped?

[https://www.cnn.com/2020/04/29/dr-anthony-fauci-says-data-from-remdesivir-coronavirus-drug-trial-shows quite-good-news.html](https://www.cnn.com/2020/04/29/dr-anthony-fauci-says-data-from-remdesivir-coronavirus-drug-trial-shows-quite-good-news.html)

From: Bozzette, Sam (NIH/NCATS) [E]
Sent: Wednesday, April 29, 2020 9:19 AM
To: Adam, Stacey (FNIH) [T] <(b) (6)> Butterson, Joan <joan (b) (6)> Collins, Sylva
 (FDA/CDER) <(b) (6)> Judy Currier <(b) (6)> De Claro, R. Angelo (FDA/CDER)
 <(b) (6)> Mark Eisner <(b) (6)> Keith Gottesdiener
 <(b) (6)> Eric Hughes <(b) (6)> LaVange, Lisa M <(b) (6)>
 Elliott Levy <(b) (6)> Sandeep Menon <(b) (6)> Amanda Peppercorn
 <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah
 (NIH/NIAID) [E] <(b) (6)> Amanda Peppercorn <(b) (6)> Price, Dionne
 (FDA/CDER) <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Shen, Yuan Li
 (FDA/CDER) <(b) (6)> Farley, John (FDA/CDER) <(b) (6)> Goff, David (NIH/NHLBI)
 [E] <(b) (6)> Vincent, Michael <(b) (6)> Wung, Peter /US
 <(b) (6)>
Cc: Mary Biggs <(b) (6)> Demarcus <(b) (6)> Macone, Erin <(b) (6)>
 Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Elizabeth Kim
 <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Butcher, Tina
 <tina (b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T]
 <(b) (6)>
Subject: Of interest re remdesivir

https://www.statnews.com/2020/04/29/gilead-says-critical-study-of-covid-19-drug-shows-patients-are-responding-to-treatment/?utm_source=STAT+Newsletters&utm_campaign=f9a2a59829-breaking_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-f9a2a59829-152058113

...Original Appointment...

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Wednesday, April 29, 2020 2:44 AM
To: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; LaVange, Lisa M; Elliott Levy; Sandeep Menon; Amanda

Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US
Cc: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina, Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]
Subject: Canceled: ACTIV TX-Clinical Master Protocol Subgroup Meeting #11
When: Wednesday, April 29, 2020 3:00 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us> (b) (6) 2
Importance: High

Dear TX-Clinical Master Protocol Subgroup,

The co-chairs and subgroup chair have decide that the best use of the group's time is to hold off and reconvene with CTC WG at 12pm ET on Thursday and as our team on Friday. For Thursday, you should have an invite from Karent Tountas for the meeting with the CTC group.

See you all Thursday!

Stacey

Join Zoom Meeting
<https://fnih.zoom.us/>

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Meeting ID: (b) (6)

Password: (b) (6)

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Dial by your location

(b) (6)

US (New York)

US (Chicago)

US

US (Houston)

US (San Jose)

US (San Jose)

US

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA74284158B86087D08B628E6F-MELENCIOC]
Sent: 6/8/2020 4:28:40 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Do sten, Mikael [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [(b) (6) Plump, Andrew [(b) (6) Stoffeis, Paul [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Coavis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) (6)
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Chen, Helen [(b) (6) Elsaid, Olivia [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskipl]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [(b) (6) Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togash m]; Zottoli, Jessica

(b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolnetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolnetzc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestys]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]

Subject: ACTIV EC & Working Group Co-Chair Meeting

Location: <https://fnih.zoom>. (b) (6)

Start: 7/15/2020 7:00:00 PM

End: 7/15/2020 8:30:00 PM

Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olvia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Miko (NIH/NCI) [E]; Zottoli, Jessica; Sepulveda, Dorina (FNIH) [T]; Burklow, John (NIH/OD) [E]; Gorman, Greta (FNIH) [T]; Hallett,

Adrienne (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Culp, Michele (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Burrus-Shaw, Cynd (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 7/2/2020 12:59:48 AM
To: Eric Hughes [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Na mish Pate (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6) Keith Gottesdiener [(b) (6) Elliott Levy [(b) (6) Wung, Peter /US [(b) (6) Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Alvarez, Rosa Maria [(b) (6) Rose Li [(b) (6) Mark Krystal [(b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Sanderson, Philip (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee2d44e63f2645708a3beb2ea1b280a1-sandersonpe]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tressler, Randall (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tresslerri]; (b) (6) Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Young, John (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Dana Carluccio [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Sumit Chanda [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; (b) (6) Draghia Akli, Ruxandra [JRDUS] [(b) (6) Hughes, Eric [(b) (6) Rich Colonno [(b) (6) Fisher, Robert (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=706cb01f58ef4042aeec4de5ab72ec1-Robert.Fish]
CC: Chen, Helen Q. [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6) Salathin, Carla [(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting

Dear ACTIV TX-Clinical Agent Prioritization Subgroup and Antiviral Subteam,

While I could not get quorum for the 12-1pm slot for our discussion tomorrow, many of you said you could be available after 3pm. Therefore, could you all let me know if 3-4pm ET tomorrow would work for you to meet?

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

From: Adam, Stacey (FNIH) [T]

Sent: Tuesday, June 30, 2020 10:55 PM

To: Eric Hughes <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Ruxandra Draghia-Akli <(b) (6)> John Mellors <(b) (6)> Naimish Patel <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Young, John <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Poole, Mike <(b) (6)> Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)> Vincent, Michael <(b) (6)> Keith Gottesdiener <(b) (6)> Elliott Levy <(b) (6)> Wung, Peter /US <(b) (6)> Koroshetz, Walter (NIH/NINDS) [E] <(b) (6)> Higgs, Elizabeth (NIH/NIAID) [E] <(b) (6)> Carlos O Garner <(b) (6)> Goff, David (NIH/NHLBI) [E] <(b) (6)>
Cc: Chen, Helen Q. <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Alvarez, Rosa Maria <(b) (6)> Salathin, Carla <(b) (6)> (b) (6) Parker, Ashley (NIH/OD) [E] <(b) (6)>

Subject: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

We would like to have a meeting on Thursday with this team and the Antiviral review subteam to discuss and finalize the Antiviral Subgroup's selections from this latest Wave of prioritization.

Please let me know if you would be able to attend this meeting from 12-1pm ET.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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APAR0000005132-2516549

To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [lcorey@fredhutch.org]; Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshov]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King]; Kurlla, Michael (NIH/NCATS) [E] [(b) (6) Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [(b) (6) Resnansky, Laura [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wachtel, Jonathan [(b) (6)]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Bascles, Lionel [(b) (6) Srinivasan, Badhri [(b) (6) Vincent, Mike [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]

CC: Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6) Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [(b) (6) Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6) Minnich, Beth [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin [(b) (6) Tolman, Brett [(b) (6) Garner, Carlos [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Hamilton, Nancy

[(b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]

Attachments: Clinical Trial Capacity Working Group Meeting Agenda_04242020.pdf

Location: <https://zoom.us/j/> (b) (6)

Start: 4/24/2020 1:00:00 PM

End: 4/24/2020 2:00:00 PM

Recurrence: (none)

Required Attendees: Bascles, Lionel; Srinivasan, Badhri; Vincent, Mike; Goff, David (NIH/NHLBI) [E]; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Woodcock, Janet (FDA/CDER); Klote, Mary

Optional Attendees: Thomas, Ashley (FDA/CDER); Sizemore, Christine (NIH/FIC) [E]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholey, David (FNIH) [T]; Criffie d, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6) Stratton, Benjamin; Tolman, Brett; Garner, Carlos

Dear Colleagues – Please find the agenda for the call attached. Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 6/10/2020 1:51:45 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]
Subject: FW: Summit follow up

Ok, four companies. And just to confirm the process, Janet Woodcock's team is handling the interactions with the companies re: their willingness to play.

From: Adam, Stacey (FNIH) [T] < > (b) (6)
Sent: Wednesday, June 10, 2020 9:37 AM
To: Wholley, David (FNIH) [T] < > (b) (6)
Subject: FW: Summit follow up

fyi

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: < > (b) (6) , Mobile: < > (b) (6)

From: Amanda Peppercorn < > (b) (6)
Sent: Wednesday, June 10, 2020 9:33 AM
To: Adam, Stacey (FNIH) [T] < > (b) (6) ; BugIn, Kevin (FDA/CDER) < > (b) (6)
Subject: Summit follow up

Hi Stacey and Kevin, on behalf of the Vir/GSK collaboration, we want to communicate to you and the ACTIV teams that we are strongly interested in participation in ACTIV3 and would like to feed back some questions/comments about the draft protocol and the potential collaboration with ACTIV. At this stage we do not believe that we will be pursuing participation in ACTIV2. Would it be appropriate to send a list of questions/comments to you both by the end of the week on the ACTIV3 proposal?

Many thanks,

Amanda

Amanda Peppercorn, M.D.
Medicine Development Leader, COVID-19 mAb program

GSK Research & Development

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Sent: 5/1/2020 3:19:09 AM
To: Eric Hughes [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Na mish Patel [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6) Keith Gottesdiener [(b) (6) Elliott Levy [(b) (6) Wung, Peter /US [(b) (6) Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)
CC: Elizabeth Kim [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]; Alvarez, Rosa Maria [(b) (6) Salathin, Carla [(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

Dear TX-Clinical Agent Prioritization Subgroup,

Thank you once again for a productive meeting.

I have heard from a few of you that as we discussed in the meeting you may need a little more time that until tomorrow due to the additional agents. **Therefore, we are extending the deadline for scoring until 12pm ET on Sunday, May 3.** We really cannot extend it further due to needing have a determination for an ACTIV Leadership Meeting early next week, so I would ask that everyone try to meet that deadline punctually.

I hope this will help with a little breathing room for scoring.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

APAR0000005552-2516552

Direct: (b) (6) | Mobile: (b) (6)

From: Adam, Stacey (FNIH) [T]

Sent: Thursday, April 30, 2020 7:05 PM

Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

Importance: High

Dear TX-Clinical Agent Prioritization Subgroup,

I appreciate the candid and productive meeting that we had today. All your feedback is very helpful to refine our process for the next time.

For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some of this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

1. The summary spreadsheets for the agents in the host targeted category that have been added from the R&D Consortium group + 1 for Firazyr as it was requested. (one note, the group shared with us Firazyr is likely be tested in a few other trials, so that may need to be considered)
2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.
3. An article relevant to immune modulator use in COVID-19.
4. Articles for the Antiviral group on some preclinical testing work.
5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but EIDD-2801.
 - a. *"All of these compounds except EIDD-2801 are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here <https://reframedb.org/assays/A00440> You can create an account for free and search the data."*

Please find attached the updated spreadsheet with all the new relevant compounds added for the groups to vote on. These new compounds for your groups are highlighted in green.

Finally, please find below the captured action items and key takeaways from the meeting.

Action Items

Action Items		
	Information	POC
1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy /
2	Send updated score sheets Agent Prioritization Review Committee members (immunomodulators) score additional agents that have been added from the R&D Consortium list	Stacey Adam Stacey Adam
3		AP Sub Group Members

Getting standardized, reliable data on the agents

- Trans-NIH information, intramural and extramural
- Mike Poole, Gates Foundation

Stacey Adam /

Ruxandra Draghia-Akli

Ask Preclinical Working Group (R&D members) for relevant data on agents if available

Joe Menetski

Get data on antivirals from NIAID and NCATS

Sarah Read/Christine Colvis

Key Takeaways

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More research needed on drugs to understand whether these are worth putting into clinical trials. Need for more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) | Mobile: (b) (6)
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNHI's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/24/2020 11:26:52 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Canceled: ACTIV TX-Clinical Master Protocol Subgroup Meeting #12
Location: <https://nih.zoom.us/> (b) (6)

Start: 4/30/2020 4:00:00 PM
End: 4/30/2020 5:00:00 PM
Show Time As: Free

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne

(FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER), Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US
Optional Attendees: Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Hi TX-Clinical MPSG,

I am canceling our zoom because we will be using Karen's group's zoom.

Thanks,

Stacey

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Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

From: Chen, Helen Q. [(b) (6)]
Sent: 6/25/2020 8:44:32 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Draghia-Akli Ruxandra [(b) (6)]; Garner, Carl (b) (6) (b) (6) . Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fid]; Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Hughes, Eric [(b) (6) Judy Curner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [naimish.patel@sanofi.com]; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis], Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [(b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa Maria [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [dana. (b) (6) Rose Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas Smalldon [(b) (6) Stratton, Benjamin [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H.lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9b4f99383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]

Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV Antivirals Candidates - Contacts Request.xlsx

Dear ACTIV TX-Clinical WG,

As mentioned during the meeting, our antivirals prioritization team is currently evaluating 11 candidates that have been submitted through the compound survey. In parallel, we would like to actively generate more survey submissions for our team to evaluate in early July.

To that end, **we need your help to identify contacts for additional candidate agents, from whom we will solicit survey submissions.** Please find attached a list of antiviral agents we've identified from public databases, as well as companies / academic institutes affiliated with those agents. Based on your network and industry knowledge, if you could help us fill out the **names and emails of individuals who would be the best contacts for the agents**, that would be much appreciated.

Please return the list to Stacey and me by noon ET tomorrow (6/26). This will allow sufficient time for the investigators to submit the compound survey in time for our next cycle of antiviral prioritization.

Feel free to reach out if you have any questions. Thank you very much!

Warm regards,
Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] <(b) (6)>

Sent: Wednesday, June 17, 2020 8:48 AM

To: Adam, Stacey (FNIH) [T]; Draghia-Akli, Ruxandra; Garner, Carl; Stein, Peter (FDA/CDER); Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (N H/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (N H/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Belgel, John (NIH) [E]

Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]
Subject: ACTIV Therapeutics-Clinical Working Group Meeting

When: Thursday, June 25, 2020 1.00 PM-2.00 PM (UTC-05.00) Eastern Time (US & Canada).

Where: <https://fnih.zoom>. (b) (6)

Dear ACTIV TX-Clinical WG,

Please find attached the slides that we will use to update on the progress on the master protocols and antiviral prioritization in the last week.

We look forward to speaking with many of you tomorrow.

Kind regards,
Stacey

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 [(b) (6)]; Doroshow, James (NIH/NCI) [E] [(b) (6) Goff, David (NIH/NHLBI) [E]
 [david. (b) (6)], Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Mensah, George (NIH/NHLBI) [E]
 [(b) (6)]; Nayak, Seema (NIH/NIAID) [E] [(b) (6)]; Payton, Manizhe (NIH/NIAID) [E]
 [(b) (6)]; Sizemore, Christine (NIH/FIC) [E] [(b) (6) Weinmann, Gail
 (NIH/NHLBI) [E] [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Tountas, Karen
 (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Vincent, Mike
 [(b) (6) Bascles, Lionel [(b) (6) Stein, Peter (FDA/CDER)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Srinivasan, Badhri
 [(b) (6) Garner, Carlos [(b) (6) Cohen, Myron
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry
 [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy
 [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James
 (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura
 [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Weinmann, Gail
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Kublin MD, MPH, James
 (b) (6) Ferguson, Sue [(b) (6)
 CC: Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Lowy, Douglas (NCI) [(b) (6) Read, Sarah
 (NIH/NIAID) [E] [(b) (6)]; Adam, Stacey (FNIH) [T] [(b) (6) Melencio, Cheryl (FNIH) [T]
 [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Menetski, Joseph (FNIH) [T]
 [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6) Santos, Michael (FNIH) [T]
 [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Hill, Zoe (NIH/NHLBI) [C] [(b) (6)];
 Pico, Dianna (NIH/NHLBI) [C] [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [(b) (6) Culp,
 Michelle (NIH/OD) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Gonzalez, Nina
 [(b) (6) Takas, Therese [(b) (6) (b) (6)
 Kenny, Dermot [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative
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 Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric
 [(b) (6)]; Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
 [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana
 [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative

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Attachments: Clinical Trial Capacity Working Group Meeting Agenda_06232020.pdf

Start: 6/23/2020 1:00:00 PM

End: 6/23/2020 2:00:00 PM

Recurrence: (none)

Required Attendees: Vincent, Mike; Bascles, Lionel; Stein, Peter (FDA/CDER); Srinivasan, Badhri; Garner, Carlos, Cohen, Myron; Corey, Larry; Davey, Victoria, Desrosiers, Betsy, Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kunlla, Mike, Mensah, George, Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Weinmann, Gail, Kublin MD, MPH, James, Ferguson, Sue

Optional Attendees: Takas, Therese; (b) (6) Kenny, Dermot; Gonzalez, Nina; Wachtel, Jonathan; Coivis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Doug as (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] (b) (6) Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Heaton, Penny; James, Stephanie; Li, Rose, Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuvevson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] (b) (6) Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]

Dear WG Colleagues, During the WG call we'll be talking about the **development of playbooks – priorities and volunteers!** We have received much positive feedback regarding the development of the first playbook for home nursing. Looking forward to this important discussion. Karen

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]

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(b) (6) Klote, Mary (Molly) (b) (6); Victoria Davey
 (b) (6) Hodes, Richard (NIH/NIA) [E] (b) (6) Bronson, Charlette (NIH/NIA) [E]
 (b) (6) Best, Cindy (NIH/NEI) [E] (b) (6); Tumminia, Santa (NIH/NEI) [E]
 (b) (6) Meltzer, Abbey (FNIH) [T] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]
 (b) (6) Koob, George (NIH/NIAAA) [E] (b) (6); Rodgers, Griffin (NIH/NIDDK)
 [E] (b) (6) Woychik, Rick (NIH/NIEHS) [E] (b) (6) Higginbotham, Aurelia
 (NIH/NIAAA) [E] (b) (6); Shapiro, Beth (NIH/NIDDK) [E] (b) (6) Eason,
 Allison (NIH/NIEHS) [E] (b) (6) Walker, Paula (NIH/NINDS) [E] (b) (6) Volkow,
 Nora (NIH/NIDA) [E] (b) (6) Glass, Roger (NIH/FIC) [E] (b) (6) Tucci, Debara
 (NIH/NIDCD) [E] (b) (6) Byrnes, Noni (NIH/CSR) [E] (b) (6) Schulke, Hilda
 (NIH/NIDA) [E] (b) (6) Stover, Kathleen (NIH/FIC) [E] (b) (6); Hamid, Khawar
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 (NIH/CIT) [E] (b) (6) (b) (6) Anita Caulfield (b) (6)
 Sharpless, Norman (NIH/NCI) [E] (b) (6) Bianchi, Diana (NIH/NICHD) [E]
 (b) (6) Ott, Sandra (NIH/NICHD) [E] (b) (6) Ramirez, Katherine (NIH/NIMHD) [C]
 (b) (6) Perez-Stable, Eliseo (NIH/NIMHD) [E] (b) (6) Council, Lisa
 (NIH/NCCIH) [E] (b) (6) Langevin, Helene (NIH/NCCIH) [E] (b) (6) v); Schwetz, Tara
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End: 7/29/2020 8:00:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lee, William; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Bancel, Stephane; Erck, Stan

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Togashi, Mieke (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; FNIH Central Account; Ripley, Nadege; Riggan, Mary; Vessey, Rupert; Lowy, Douglas (NIH/NCI) [E]; Gorman, Greta (FNIH) [T]; Lucas Smalldon; Klote, Mary (Molly); Victoria Davey; Hodes, Richard (NIH/NIA) [E]; Bronson, Charlette (NIH/NIA) [E]; Best, Cindy (NIH/NEI) [E]; Tumminia, Santa (NIH/NEI) [E]; Meltzer, Abbey (FNIH) [T]; Koroshetz, Walter (NIH/NINDS) [E]; Koob, George (NIH/NIAAA) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Woychik, Rick (NIH/NIEHS) [E]; Higginbotham, Aurelia (NIH/NIAAA) [E]; Shapiro, Beth (NIH/NIDDK) [E]; Eason, Allison (NIH/NIEHS) [E]; Walker, Paula (NIH/NINDS) [E]; Volkow, Nora (NIH/NIDA) [E]; Glass, Roger (NIH/FIC) [E]; Tucci, Debara (NIH/NIDCD) [E]; Byrnes, Noni (NIH/CSR) [E]; Schulke, Hilda (NIH/NIDA) [E]; Stover, Kathleen (NIH/FIC) [E]; Hamid, Khawar (NIH/CSR) [E]; Norris, Andrea (NIH/CIT) [E]; Wade, Portia (NIH/CIT) [E]; (b) (6) Anita Caulfield; Sharpless, Norman (NIH/NCI) [E]; Bianchi,

Diana (NIH/NICHD) [E]; Ott, Sandra (NIH/NICHD) [E]; Ramirez, Katherine (NIH/NIMHD) [C]; Perez-Stable, Eliseo (NIH/NIMHD) [E]; Council, Lisa (NIH/NCCIH) [E]; Langevin, Helene (NIH/NCCIH) [E]; Schwetz, Tara (NIH/OD) [E]; Dzokoto-Pomenya, Caroline (NIH/OD) [C]

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[(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Dave Frankowski [(b) (6) Baric, Toni C
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
Mason, Stephen [(b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Attachments: 2020-09-23_Preclinical_WG_Summary_V1.docx

Dear Working group members,

Here are the minutes from last week's full working group meeting for your review. Please let me know if there are any changes. Sorry these are late.

Joe